IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

[UNDER SEAL]	:	CIVIL ACTION NO.: 9:14-CV-00230-RMG
	:	HON. RICHARD M. GERGEL
Plaintiffs	:	
	:	
v.	:	FILED IN CAMERA AND
	:	UNDER SEAL PURSUANT
	:	TO 31 U.S.C. § 3730(b)(2)
	:	
[UNDER SEAL]	:	
	:	JURY TRIAL DEMANDED
Defendants.	:	

SEVERED SECOND AMENDED QUI TAM COMPLAINT

MATTER FILED UNDER SEAL

DO NOT FILE WITH PACER

DO NOT SERVE ON DEFENDANTS

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UNITED STATES OF AMERICA and THE STATES OF NORTH CAROLINA, CALIFORNIA, ILLINOIS, EX REL. SCARLETT LUTZ and KAYLA WEBSTER, Plaintiffs/Relators, v. HEALTH DIAGNOSTIC LABORATORY, INC., SINGULEX, INC., and BLUEWAVE HEALTHCARE CONSULTANTS, INC., LATONYA MALLORY, PHILIPPE J. GOIX, PhD, FLOYD CALHOUN DENT, III and ROBERT BRADFORD JOHNSON Defendants.	CA No.: 9:14-cv-00230-RMG HON. RICHARD M. GERGEL SEVERED SECOND AMENDED QUI TAM COMPLAINT JURY TRIAL DEMANDED **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

I. INTRODUCTION

This *qui tam* action alleges violations of the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and analogous state False Claims Acts, related to a clinical laboratory testing scheme carried out by the Defendants Health Diagnostic Laboratory, Inc. ("HDL"), Singulex, Inc. ("Singulex"), BlueWave Healthcare Consultants, Inc. ("BlueWave"), LaTonya Mallory, Philippe J. Goix, Floyd Calhoun Dent, III, and Robert Bradford Johnson. Defendants HDL and Singulex provide illegal financial inducements to physicians in exchange for referrals of patients for laboratory testing. Defendants HDL's and Singulex's financial relationships with referring physicians violate federal and state anti-kickback statutes, and analogous state laws prohibiting physician self-referrals. Much of the laboratory testing referred to HDL and Singulex is also not medically necessary. Defendant BlueWave conspires with HDL and Singulex to violate the federal False Claims Act and the analogous state False Claims Acts by facilitating HDL's and

Singulex's offers of illegal inducements to physicians and the referral of patients by physicians to HDL and Singulex labs. Relators also bring this action against HDL's CEO, LaTonya Mallory, Singulex's former CEO, Philippe J. Goix, and the owners of BlueWave, Floyd Calhoun Dent, III and Robert Bradford Johnson, for their roles in directing and supervising the fraudulent conduct. Relators also allege violations by HDL and Singulex of the California Insurance Frauds Prevention Act ("CIFPA"), Cal. Ins. Code § 1871, *et seq*; and the Illinois Insurance Claims Fraud Prevention Act ("ILCFPA"), 740 Ill. Comp. Stat. § 92/1, *et seq*.

Qui Tam Plaintiffs ("Relators") Lutz and Webster, through their legal counsel, William J. Tuck, P.A., Pietragallo Gordon Alfano Bosick & Raspanti, LLP, and Wyatt & Blake, L.L.P., bring this action on their own behalf, and on behalf of the United States of America and the States of North Carolina, California, Illinois (hereafter "the Government"). These States, along with the United States, are hereafter collectively referred to as the "Government."

1. This is an action to recover monetary damages and civil penalties on behalf of the United States of America and the States of North Carolina, California and Illinois, arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used, or presented by Defendants HDL, Singulex and BlueWave. ("the Corporate Defendants"), and/or their agents, predecessors, successors, and employees, including Defendants LaTonya Mallory, Philippe J. Goix, Floyd Calhoun Dent, III, and Robert Bradford Johnson ("the Individual Defendants") in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended ("the federal FCA"). This action also arises under the false claims acts of the States of North Carolina, California and Illinois. This action also arises under the CIFPA and ILCFPA, private insurance *qui tam* statutes in the States of California and Illinois, respectively.

2. Defendants HDL and Singulex are nationwide providers of clinical laboratory testing services. Many of the patients receiving their services are beneficiaries of myriad Government programs, including, but not limited to, the Medicare, TRICARE/CHAMPUS, numerous Medicaid programs and other state funded healthcare programs. A significant number of patients receiving these services are insured by myriad private insurers, including patients who are residents of California and/or Illinois.

3. Defendants' unlawful scheme is wide reaching but straightforward. Defendants HDL and Singulex, under the supervision and direction of their CEOs, Defendants LaTonya Mallory and Philippe J. Goix, offer cash remuneration to physicians to induce them to refer patients to Defendants HDL and Singulex for laboratory testing related to high cholesterol and predicting risk factors for coronary disease. Defendant HDL offers physicians $20.00 per patient referral. Defendant Singulex offers physicians $10.00 for each patient referred. Both HDL and Singulex attempt to disguise these illegal remunerations through sham "processing fee" arrangements with referring physicians. A physician who refers a patient to both HDL and Singulex receives a total of $30.00 in "processing fees" each time the patient is tested.

4. Since its founding in 2009, Defendant BlueWave has been the exclusive marketing agent for Defendants HDL and Singulex. Under the direction of BlueWave founders and owners, Floyd Calhoun Dent, III and Robert Bradford Johnson, BlueWave representatives promote HDL and Singulex services to physicians, including lucrative offers to pay sham "processing fees" to referring physicians.

5. Physicians have referred and continue to refer patients to HDL and Singulex in exchange for these inducements.

6. One purpose of the inducements offered by Defendants is to obtain referrals from targeted physicians. Therefore, all claims submitted to Government healthcare programs or to private insurers in California and Illinois by HDL and Singulex that are tainted by the fraudulent kickback scheme are false claims.

7. The fees paid by HDL and Singulex to referring physicians ($20 and $10 per referral) greatly exceed fair market value of any services performed by referring physicians. Also, compensation paid by HDL and Singulex to physicians ($20 or $10 times number of patients referred) is based on the volume of referrals.

8. Defendants violate the federal FCA by submitting or causing the submission of claims for laboratory testing tainted by their fraudulent conduct, and by creating false or fraudulent records material to false claims.

9. Defendants have further violated the FCAs of the States of North Carolina, California and Illinois in the same manner they violated the federal FCA.

10. In addition, Defendants have violated federal and state FCAs by conspiring to submit or to cause the submission of false claims by Defendants HDL and Singulex for these illegally induced laboratory tests to state healthcare programs, including Medicaid, and by conspiring to create or use false records material to the false or fraudulent claims for laboratory testing services submitted by Defendants HDL and Singulex to state health care programs, including Medicaid.

11. Having submitted, or caused the submission of, these false claims to federal and state health care programs, Defendants HDL and Singulex violated the federal and state FCAs by failing to return to state and federal government healthcare programs overpayments associated with illegally obtained state and federal funds.

12. The Defendants' national scheme caused further damage to Government healthcare programs, in addition to the reimbursements for the illegally induced, and in many cases, medically unnecessary tests themselves. The Defendants' scheme caused beneficiaries of Government healthcare programs and private insurance plans in California and Illinois to receive other unnecessary healthcare, including follow-up physician visits, follow-up testing, and unnecessary medications related to the illegal referrals to HDL and Singulex.

13. The Defendants' kickback scheme also violates Section 1871.7(a) of the CIFPA, Cal. Ins. Code 1871.7(a), and Section 92/5(a) of the ILCFPA 740 Ill. Comp. Stat. § 92/5(a), Defendants have entered into illegal arrangements with physicians that provide financial incentives for the use of their laboratory services, resulting in medically unnecessary testing that is then billed to private insurers.

14. The Defendants' operations extend across the United States, and the Defendants' scheme is national in scope. Defendants BlueWave, Floyd Calhoun Dent, III and Robert Bradford Johnson, as the marketing agents for HDL and Singulex, operate wherever HDL and Singulex do business nationwide.

15. Relators have observed the scheme employed by the Defendants operating in the office of Lloyd Miller, MD, a customer of Defendants HDL and Singulex. Dr. Miller's practice is located within the sales territory of BlueWave representatives serving parts of North Carolina, South Carolina, and Georgia.

16. BlueWave's founder and owner, Defendant Floyd Calhoun Dent, III, and BlueWave's representatives promoted the HDL and Singulex inducements to Dr. Miller. The owners of BlueWave, Defendants Floyd Calhoun Dent, III and Robert Bradford Johnson,

employed HDL and Singulex nationwide marketing practices that centered on offering physicians inducements in exchange for patient referrals.

II. JURISDICTION AND VENUE

17. This action arises under the laws of the United States of America to redress violations of the federal FCA, 31 U.S.C. § 3729 *et seq*. Defendants do business in the District of South Carolina, the Western District of North Carolina, and throughout the United States. The acts proscribed by 31 USC § 3729(a) and described in this *qui tam* complaint occurred in the District of South Carolina, Western District of North Carolina, and elsewhere in the United States.

18. Subject-matter jurisdiction over this *qui tam* action is conferred by 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730(b). Relator Lutz and Relator Webster are each an "original source" and otherwise authorized to maintain this action in the name of the United States and as contemplated by the Civil False Claims Act, 31 U.S.C. §§ 3729-33, and in the name of the other named Plaintiff states.

19. Relators have made the necessary voluntary disclosures to the Governments prior to the filing of this lawsuit and have filed all documents necessary with the United States Government as required by 31 U.S.C. § 3730(b)(2). Relators have also made all voluntary disclosures to the States of North Carolina, California and Illinois prior to the filing of this lawsuit and have filed all necessary documents with these States as required by each state's FCA and by the CIFPA and ILCFPA.

20. The Court has jurisdiction over Defendants' violations of the false claims statutes of the States of North Carolina, California and Illinois, as well as the CIFPA and ILCFPA pursuant to 31 U.S.C. § 3732(b), because Defendants' violations of these state acts and their violations of the federal FCA arise from the same transactions or occurrences.

21. There has been no public disclosure of the "allegations or transactions" in this Complaint under Section 3730(e) of the federal FCA or under analogous provisions of the named state FCAs. The specific facts, circumstances, and allegations of the Defendants' violations of the federal and state False Claims Acts and the CIFPA and ILCFPA have not been publicly disclosed in a civil suit or administrative civil money penalty proceedings in which the Government is already a party. Relators, moreover, would qualify as an "original source" of the allegations in this Qui Tam Complaint under 31 U.S.C. § 3730(e) of the federal FCA, and under provisions of relevant state FCAs and the CIFPA and ILCFPA even had such a public disclosure occurred.

22. The Court has personal jurisdiction over all of the Defendants because 31 U.S.C. § 3732(a) authorizes nationwide service of process, and because the Defendants have minimum contacts with the United States, and can be found in, transact or have transacted, business in the District of South Carolina and the Western District of North Carolina.

23. Defendants regularly perform healthcare services in and submit or cause the submission of thousands of claims for payment to federal and state health care programs, including, but not limited to, Medicare and Medicaid, and accordingly, are subject to the jurisdiction of this Court.

24. Venue lies under 28 U.S.C. § 1391(b), (c) and 31 U.S.C. § 3732(a) because the Western District of North Carolina and the District of South Carolina are districts in which any one Defendant can be found or transacts business, and an act proscribed by 31 U.S.C. § 3729 occurred within this district.

25. The Court has supplemental jurisdiction, pursuant to 28 U.S.C. § 1367, over the causes of action brought under the laws of the States of North Carolina, California and Illinois,

for the recovery of funds paid by a State Government or by a private insurer because these arise from the same facts forming the basis of the action brought under 31 U.S.C. § 3730.

III. PROCEDURAL HISTORY

26. On February 6, 2013, Qui Tam Relators filed their Original Complaint, under seal in the United States District Court for the Western District of North Carolina.

27. Pursuant to this Court's Order, and the federal False Claims Act, 31 U.S.C. § 3730(b), this case has remained under seal while the United States and the named states have investigated the allegations in Relators' Complaint.

28. In the fall of 2013, in the midst of the various governments' investigations, the United States Department of Justice requested that Relators consent to the United States' request to transfer this matter to the District of South Carolina.

29. Pursuant to the request by the United States, on January 24, 2014, Relators and the United States filed a joint motion to transfer this action to the District of South Carolina.

30. On January 27, 2014, the United States District Court for the Western District of North Carolina granted the United States' and Relators' request pursuant to 28 U.S.C. § 1404(a) and entered an Order granting the motion to transfer this case, including the Complaint and all pleadings, and directing that all pleadings and matters filed remain under seal.

IV. THE PARTIES

A. Relators Lutz and Webster

31. Qui Tam Relator Scarlett Lutz ("Relator Lutz") is an individual residing in Florence, South Carolina.

32. Relator Lutz is the owner and operator of Palmetto Billing Services, 900 W. Evans Street, Florence, SC 29501.

33. From March of 2011 until September of 2011, Relator Lutz provided billing services to Dr. Lloyd Miller, MD ("Dr. Miller"), a primary care physician in Florence, SC. During this time, Relator Lutz learned of Defendants' efforts to provide inducements to physicians, as well as Dr. Miller's billing practices including billings to government healthcare programs and private insurers for patient blood draws for clinical laboratory testing.

34. Qui Tam Relator Kayla Webster, RN ("Relator Webster") is an individual residing in Timmonsville, South Carolina.

35. Relator Webster received a B.S. in Nursing from Francis Marion University in Florence, South Carolina in May 2008. Since that same time, Relator has been employed as a registered nurse.

36. Relator Webster has worked part time as a registered nurse for Comfort Keepers, a home health agency in Florence, South Carolina. In that capacity, she performs home visits and patient assessments.

37. Since her graduation from college until late July 2013, Relator Webster's main employment has been as the Nursing Supervisor for Dr. Miller. In that capacity, Relator Webster has interacted with patients on a daily basis, performed clinical services, including triage, provided assistance with prescription medications, and reviewed patient lab test results (including HDL and Singulex). Relator Webster has also interacted with insurers on a variety of issues, including prior authorizations.

38. Through her experience as Nursing Supervisor for Dr. Miller, Relator Webster has knowledge of the Defendants' marketing efforts and practices. She also has knowledge of inducements offered by HDL and Singulex to referring physicians, as well as Dr. Miller's practices with regard to patient referrals and patient blood draws for clinical laboratory testing.

39. Relators have direct and independent knowledge of the factual allegations contained in this Qui Tam Complaint and each of them brings this action as an "original source," as that term is defined by the state and federal governments' false claims acts.

B. The Defendants

1. Defendants Health Diagnostic Laboratory, Inc. ("HDL") and LaTonya Mallory

40. Defendant Health Diagnostic Laboratory, Inc. ("HDL") is a Virginia for-profit corporation with a principal place of business at 737 N. 5th Street, Suite 103, Richmond, VA 23219. HDL is one of the leading providers in the United States of clinical laboratory testing for risk factors and biomarkers for cardiovascular and related diseases.

41. HDL is a privately held company which was formed in November of 2008. HDL started testing operations in November 2009. During the first quarter of 2010, HDL processed approximately 150 samples a day. By the end of 2011, Defendant HDL was running tests on about 2,700 samples daily.

42. Currently, HDL serves approximately 10,000 physicians and one million patients. HDL's explosive growth is also illustrated through the size of its workforce. HDL has transitioned from just a handful of employees in 2009 to about 500 employees today.

43. HDL's expected revenues for 2012 are approximately $250 million. The company grew at a rate of about 5 percent per week in 2010 and 2011.

44. HDL transacts business in 45 states throughout the United States, including within the Western District of North Carolina and the District of South Carolina. HDL derives a significant portion of its revenues from Medicare and Medicaid reimbursements. Its National Provider Identifier ("NPI") is 1629209853. HDL also derives substantial revenues from private insurers, including private healthcare insurers in California and Illinois.

45. HDL hosts continuing medical education ("CME") courses to promote its products in various locations throughout the United States. On November 10, 2012, HDL hosted the CME course "Beating Cardiovascular Disease: Understanding the Meaning and Value of Key Risk Factors" in Charlotte, North Carolina. The speaker, Sam Fillingane, D.O., is a family doctor from Jackson, Mississippi who "partners advanced laboratories," including Defendant HDL.

46. HDL executives include Defendant LaTonya ("Tonya") Mallory its President, CEO, and co-founder. Ms. Mallory has extensive experience in medical devices, clinical laboratory, FDA and CLIA regulations, and clinical trials.

47. Relators believe that, at all times relevant to this Complaint, Ms. Mallory was directly involved in HDL's scheme to provide cash remuneration to referring physicians. In fact, as described herein, Defendant Mallory signed HDL's inducement payment checks to referring physicians, including Dr. Miller.

a. HDL Testing for Risk Factors for Cardiovascular Disease

48. HDL claims that its clinical laboratory testing services identify factors contributing to cardiovascular disease, provide a basis for effective treatment, and allow physicians to more effectively manage their patients. As an added value, HDL provides patients with a personalized overview of their risk factors and optional counseling from expert Health Coaches at no additional cost to the patient or their physician.

49. The relevant tests included in Defendant HDL's baseline testing panel, the relevant CPT codes and the Medicare reimbursement rates for 2012, are as follows:

CPT CODE	TEST	SC MEDICARE REIMBURSEMENT RATE	NC MEDICARE REIMBURSEMENT RATE
80061	ApoB	$13.88	$18.97
83876	MPO (Myeloperoxidase)	$48.08	$48.08

83704 83704	LDL-P HDL-P	$44.69 -	$44.69 -
83700	sdLDL	$15.95	$15.95
82541	Omega 3	$25.57	$25.57
82172	Apo A-1	$15.28	$21.95
83520	Galectin 3	$18.34	$18.34
82664	HDL 2 (subclass)	$8.43	$48.66
83695	Lp(a) mass w/reflex to Lp(a) cholesterol	$18.34	$18.34
83891*, 83892, 83896, 83903, 83908, 83912*	Apo E Genotype	$5.68, $5.68, $5.68, $23.74, $23.74, $5.68	$5.68, $5.68, $5.68, $5.84, $5.84, $5.68
83891, 83892, 83896, 83903, 83908, 83912	Factor V Leiden	$5.68, $5.68, $5.68, $23.74, $23.74, $5.68	$5.68, $5.68, $5.68, $5.84, $5.84, $5.68
83891, 83892, 83896, 83903, 83908, 83912	Prothrombin	$5.68, $5.68, $5.68, $23.74, $23.74, $5.68	$5.68, $5.68, $5.68, $5.84, $5.84, $5.68
83891, 83892, 83896, 83903, 83908, 83912	Cyp2C19	$5.68, $5.68, $5.68, $23.74, $23.74, $5.68	$5.68, $5.68, $5.68, $5.84, $5.84, $5.68
83698	Lp-PLA2	$48.08	$48.08
86141	hs-CRP	$18.34	$18.34
85384	Fibronogen	$11.09	$12.03
82726	FFA/NEFA	$25.57	$25.57
83880	NT-proBNP	$48.08	$48.08
83525	Insulin	$16.19	$16.19
82607	Vitamin B-12	$21.35	$21.35
82747	RBC Folate	$24.53	$21.34
83891, 83892, 83896, 83903, 83908, 83912	MTHFR Genotype	$5.68, $5.68, $5.68, $23.74, $23.74, $5.68	$5.68, $5.68, $5.68, $5.84, $5.84, $5.68
TOTAL REIMBURSEMENT		$727.35	$599.09

* = Only billed once per panel; other codes billed for each test.

50. However, HDL testing can be more expensive. For example, testing services performed for E.S.Z., a Medicare patient living in South Carolina referred to HDL by Dr. Miller on January 4, 2011, consisted of the following:

CPT CODE	TEST	AMOUNT BILLED	MEDICARE PAYMENT
80061	Lipid Panel	$46.00	$0.00
82726	Long Chain Fatty Acids	$58.00	$25.41
82664	Electrophoretic Test	$69.00	$44.97
83695	Assay of Lipoprotein(a)	$44.00	$18.22
83698	Assay Lipoprotein pla2	$110.00	$0.00
83701	Lipoprotein bld hr fraction	$67.00	$34.93
83876	Assay myeloperoxidase	$113.00	$47.77
83891	Molecule isolate nucleic	$13.00	$5.51
83892	Molecular diagnostics	$78.00	$33.06
83896	Molecular diagnostics	$130.00	$55.10
83903	Molecule mutation scan	$440.00	$188.64
83908	Nucleic acid signal ampli	$275.00	$117.90
83912	Genetic examination	$13.00	$5.51
TOTAL		$1456.00	$577.02

51. Patient ESZ's records demonstrate that Medicare (and presumably other insurers and patients without insurance) can be billed more than $1,400 for an HDL testing episode. Upon information and belief, the total reimbursement for ESZ's testing (approximately $577) would be the normal range for the tests HDL usually performs for Dr. Miller's patients.

52. During 2012, HDL began offering the EarlyCDT-Lung test, a blood test to aid in the early detection of lung cancer in high risk patients, including long-term smokers and ex-smokers, by focusing on tumor antigens involved in the development of lung cancer. The CPT Code for HDL's EarlyCDT-Lung test is 83520, and the Medicare reimbursement is $18.34. Although offered by HDL, the EarlyCDT-Lung test is actually performed by OncImmune (USA) LLC.

53. HDL does business with a number of commercial insurance providers in California and Illinois, including but not limited to AETNA and Blue Cross.

54. Under process and handling agreements with referring physicians, HDL pays referral fees for patients covered by commercial insurance and government payors, including Medicare, TRICARE, and Medicaid.

2. **Defendants Singulex, Inc. ("Singulex") and Philippe J. Goix**

55. Defendant Singulex, Inc. is a Delaware for-profit corporation. Singulex's laboratory is headquartered at 1650 Harbor Bay Parkway, Suite 200, Alameda, CA 94502, USA, Telephone Number: (888) 995-6123. Singulex is privately held.

56. Singulex claims to be a "Leader in Advanced Cardiovascular Monitoring," by providing "high-value, advanced tests for the diagnosis and monitoring of chronic diseases." Singulex claims that its testing services improve patient care and reduce healthcare costs, and also "empower physicians and patients to better manage heart health" by "providing physicians with information that can allow them to earlier diagnose, better monitor, and more effectively manage chronic disease progression prior to the onset of acute clinical symptoms."

57. Singulex laboratory testing that is relevant to this *qui tam* complaint includes Singulex's Advanced Cardiovascular disease (CVD) Testing Menu, which includes tests for Cardiopathology/Heart Function and Vascular Inflammation.

58. In 2010, Singulex reported just under $5 million in revenues. Singulex launched its Advanced CVD Monitoring testing services in July of 2010, through the marketing efforts of Defendants BlueWave, Floyd Calhoun Dent, III, and Robert Bradford Johnson. In July of 2011, Singulex and BlueWave entered into an agreement for BlueWave to market both the Singulex Advanced (BlueWave) Panel and thyroid-related tests.

59. Singulex has benefitted from exponential growth related to Advanced CVD Monitoring testing services. By 2011, Singulex's earnings increased five times, with revenues of nearly $25 million (17% of which represented Medicare reimbursements). For the first six months of 2012 alone, Singulex reported approximately $20.5 million in revenues, of which 19% was derived from Medicare reimbursements. Singulex also derives a significant portion of its revenues from state Medicaid program reimbursements and from private insurance companies, including companies in California and Illinois. Defendant Singulex currently does business in 28 states. Singulex's NPI is 1184859191.

60. Singulex Advanced Panel, which allegedly determines a patient's cardiac risk, includes, but is not limited to, the following tests:

CPT CODE	TEST	SOUTH CAROLINA MEDICARE REIMBURSEMENT RATE	NORTH CAROLINA MEDICARE REIMBURSEMENT RATE
84484	Cardiac Troponin-I	$13.94	$13.94
83520	Interleukin-6	$18.34	$18.34
83520	Interleukin-17A	-	-
TOTAL		$32.28	$32.28

61. Many of the Singulex requisition forms show that Dr. Miller refers most of his patients to Defendant Singulex for the Singulex Advanced Panel.

62. Singulex executives have included Philippe J. Goix, Ph.D., the former President and CEO, and a member of Singulex's Board of Directors. Singulex's CEO Goix had executed the "processing agreements" between Singulex and referring physicians.

63. Other officers of Singulex have included . . REDACTED , and Gary S. Tom, former Vice President and General Manager of Clinical Laboratory Sales and Support.

Goix and Tom executed the exclusive sales agreement with BlueWave. REDACTED has signed Singulex's inducement payment checks to referring physicians, including Dr. Miller.

64. HDL does business with a number of commercial insurance providers in California and Illinois, including but not limited to AETNA and Blue Cross.

65. Under process and handling agreements with referring physicians, HDL pays referral fees for patients covered by commercial insurance and government payors, including Medicare, TRICARE, and Medicaid.

66. Neither HDL nor Singulex employs laboratory technicians to draw blood from patients referred to them by physicians. Instead, HDL and Singulex blood samples are drawn, processed, and shipped to HDL and Singulex laboratories by independent laboratories or by physicians who employ their own phlebotomist/lab technician.

3. Defendants BlueWave Healthcare Consultants, Inc. ("BlueWave"), Floyd Calhoun Dent, III and Robert Bradford Johnson

67. Defendant BlueWave Healthcare Consultants, Inc. ("BlueWave") is an Alabama for-profit corporation with a principal address of 307 Commercial Street SE, Hanceville, AL 35077.

68. Neither Defendant HDL nor Defendant Singulex employs a substantial sales force. Instead, Defendants BlueWave, Floyd Calhoun Dent, III and Robert Bradford Johnson perform virtually all marketing for Defendants HDL and Singulex by contracting with sales representatives to promote the products of Defendants Singulex and HDL to physicians and physician practices throughout the country. For example, BlueWave is identified as a "strategic partner" on Defendant HDL's website.

69. Defendant Floyd Calhoun "Cal" Dent, III, ("Dent") and Defendant Robert Bradford "Brad" Johnson ("Johnson") are co-owners of BlueWave. Johnson is the President and

50% owner of Defendant BlueWave. He is also an equity owner of Defendant Singulex. Dent also owns 50% of BlueWave. Dent also owns Hisway of South Carolina, Inc., which was incorporated on March 3, 2010.

70. As agents for BlueWave, Defendants Johnson and Dent both also actively market the products of Defendants Singulex and HDL. For example, Dent promotes HDL and Singulex testing services to physicians in North Carolina, South Carolina, and Georgia.

71. Thomas Anthony "Tony" Carnaggio ("Carnaggio") is an independent contractor for Defendants BlueWave, Dent and Johnson. With Dent, Carnaggio actively promotes HDL and Singulex laboratory testing services to physicians in North Carolina, South Carolina, and Georgia.

72. BlueWave marketing representatives are largely independent contractors. Upon information and belief, BlueWave representatives form corporations throughout the United States through which they receive sales commissions from BlueWave, Dent and/or Johnson for promoting HDL and Singulex products. For example, Defendant Dent formed two South Carolina companies, Hisway of South Carolina, Inc. (March 3, 2010) and AROC Enterprises, LLC (December 2010). Tony Carnaggio has formed several companies since BlueWave began promoting HDL and Singulex products in 2010: Southeast Healthcare Consultants, LLC (4/12/2010); Southeast Medical Consultants, LLC (6/27/2011); and East Coast Medical Consultants, LLC (5/16/2012).

73. Other independent contractors who market HDL and Singulex products include Kyle J. Martel, a BlueWave representative based in Florida. Mr. Martel has formed a number of Florida corporations since he began marketing HDL and Singulex products: Disease Testing & Management, LLC (June 30, 2010); and C& K Healthcare Consultants, LLC (April 6, 2012). Mr.

Martel formed C&K Healthcare Consultants with Charles A. Maimone, Jr. of Cherry Hill, NJ. Upon information and belief, all BlueWave sales representatives, such as Mr. Maimone, promote HDL and Singulex products, as an agent of Defendants BlueWave, Dent and/or Johnson. Upon information and belief, Mr. Maimone's sales territory includes Pennsylvania and New Jersey.

V. BACKGROUND ON FEDERAL AND STATE HEALTH CARE PROGRAMS

A. The Medicare Program

1. Medicare Payments: Only Medically Necessary Services

74. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for: people age 65 or older; people under age 65 with certain disabilities; and people of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).

75. Payments from the Medicare Program come from a trust fund – known as the Medicare Trust Fund – which is funded through payroll deductions taken from the work force, in addition to government contributions. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

76. The Medicare Program is administered through the United States Department of Health and Human Services ("HHS") and, specifically, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal government (particularly CMS).

77. Medicare now has four parts: Part A (Hospital Insurance); Part B (Medical Insurance); Part C (Managed Care Plans); and the recently enacted Part D (Prescription Drug) Program.

78. Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). Medicare Part A also helps cover hospice care and some home health care.

79. Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care, including emergency care. Part B helps pay for covered health services and supplies when they are medically necessary. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

80. Medicare Part D (Prescription Drug Plan) provides beneficiaries with assistance in paying for out-patient prescription drugs. Under Medicare Part D, Medicare beneficiaries must affirmatively enroll in one of many hundreds of Part D plans ("Part D Sponsors") offered by private companies that contract with the federal government. Part D Sponsors are charged with and responsible for accepting Medicare Part D prescription claims, determining coverage, and making payments from the Medicare Part D funds.

81. Payments from the Medicare Program come from a trust fund – known as the Medicare Trust Fund – which is funded through payroll deductions taken from the work force, in addition to government contributions. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

82. The Medicare Program is administered through the United States Department of Health and Human Services ("HHS") and, specifically, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal government (particularly CMS).

83. Under Medicare Part B, the federal government contracts with insurance companies and other organizations known as "carriers" or "Medicare Administrative Contractors" (MACs) to handle payment for physicians' services in specific geographic areas. These private insurance companies, or "Medicare Carriers," are charged with and responsible for accepting Medicare claims, determining coverage and making payments from the Medicare Trust Fund. Laboratory testing provided on an out-patient basis is typically covered through Medicare Part B.

84. The principal function of Medicare intermediaries and carriers is to pay the claims of Medicare providers, and to audit such claims to ensure that providers follow the strictures of the Medicare Program.

85. The Medicare carriers who receive laboratory testing claims at issue here are: for HDL in Virginia, Palmetto GBA (11302, MAC-Part B); for Singulex in Northern California, Palmetto GBA (01102, MAC-Part B); and for LabCorp in North Carolina, Palmetto GBA (11502, MAC-Part B).

86. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare payment may not be made for services that are not reasonable and necessary. To participate in Medicare, providers must assure that their services are provided economically and only when, and to the

extent, they are medically necessary. Medicare will only reimburse costs for medical services that are needed for the prevention, diagnosis, or treatment of a specific illness or injury.

87. As a condition for Medicare payment, a physician must certify the necessity of the services and, in some instances, recertify the continued need for those services. *See* Sections 1814(a)(2) and 1835(a)(2) of the Social Security Act; *see also* 42 C.F.R. § 424.10. In order for the federal government to cover Medicare Part A, Medicare Part B, or a Medicare Part C plan to provide coverage, all care must be "medically necessary."

88. Medical care is "medically necessary" when it is ordered or prescribed by a licensed physician or other authorized medical provider, and Medicare (or a Medicare Part C plan) agrees that the care is necessary and proper. Services or supplies that are needed for the diagnosis or treatment of a medical condition must meet the standards of good medical practice in the local area.

2. Medicare Only Pays for Medically Necessary Clinical Laboratory Testing

89. Medicare Part B pays for clinical laboratory testing performed by companies such as Defendants HDL and Singulex. These independent laboratories perform testing on specimens (also known as "samples") from patients referred to the "independent" laboratory by his or her physician.

90. As a condition of payment by Medicare, diagnostic laboratory tests must be ordered by a physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem. The physician must also use the results in the management of the beneficiary's specific medical problem. 42 C.F.R. § 410.32(a).

91. Medicare does not cover purely prophylactic lipid testing (lipid screening):

> Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.
>
> Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

The Medicare National Coverage Determination on Lipid Testing National Coverage Determination (NCD) for Lipid Testing (190.23), available at http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=102&ncdver=2&bc=AAEAAAAAAAAA&.

92. But when a patient is placed on dietary therapy or prescribed medication for high cholesterol, Medicare pays for periodic lipid testing. Medicare will cover "[a]ny one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy... If no dietary or pharmacological therapy is advised, monitoring is not necessary." National Coverage Determination (NCD) for Lipid Testing (190.23). Medicare also pays for lipid testing once annually for patients on "long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels." Id.

93. The physician who orders clinical laboratory services "must maintain documentation of medical necessity in the beneficiary's medical record." 42 C.F.R. § 410.32(d)(2).

3. The Independent Laboratory Bills Medicare for Testing Services

94. The majority of laboratory testing services are paid by Medicare on a fee-for service ("FFS") basis. Medicare pays for most outpatient clinical laboratory services based on the Clinical Laboratory Fee Schedule in accordance with Section 1833(h) of the Social Security

Act. The Medicare payment to the laboratory is the lesser of the laboratory's actual charge, the local fee for a geographic area, or a national limit. In accordance with the Social Security Act, national limits are set at a percent of the median of all local fee schedule amounts for each laboratory test code. Each year, fees are updated for inflation based on the percentage change in the Consumer Price Index. However, legislation by Congress can modify the update to the fees. Thus, under the Clinical Laboratory Fee Schedule, the amount paid to the lab is usually National Limitation Amount (NLA). Medicare Claims Processing Manual [Pub. 100-4] Chapter 16, Section 20. The Clinical Laboratory Fee Schedule is updated annually.

95. The clinical laboratory that provides the testing services bills the Government health programs directly, including Medicare. Medicare Part B pays approximately 80 percent of the Medicare-approved amount for these testing services.

96. The laboratory bills Medicare from the location the test is performed.

97. A clinical laboratory must accept assignment of the Medicare beneficiary's benefit in order to receive Part B payment for laboratory tests based on the Laboratory Fee Schedule. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 30.1 - Mandatory Assignment for Laboratory Tests. Thus, Part B deductible and coinsurance (co-payments) do not apply to laboratory services provided by a physician or by an independent laboratory. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation.

98. The clinical laboratory submitting the claim to a federal healthcare program must maintain documentation it receives from the ordering physician, as well as documentation that the information that the lab submitted with the claim accurately reflects the information it received from the ordering physician or non-physician practitioner. 42 C.F.R. § 410.32(d)(2)(ii).

99. During claims review, CMS may deny claims by laboratories where documentation provided does not demonstrate that the service is reasonable and necessary, or where the providers fail to provide documentation requested to establish medical necessity. 42 C.F.R. § 410.32(d)(3)(ii).

100. The entity submitting the claim may request from the referring physician additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s). 42 C.F.R. § 410.32(d)(3)(iii).

101. If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the carrier is assured that the physician prescribes such services only when the criteria are met. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.2.

4. Limits on Medicare Payments for Blood Draws (Venipuncture)

102. In addition to payment for the laboratory testing service itself, CMS may make a separate payment to providers for collection of the specimen. Medicare reimburses medical providers a specimen collection fee for drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.

a. **Medicare Pays for Blood Draws (Venipuncture) by a Physician**

103. Medicare reimburses a physician for a blood specimen collection (venipuncture) only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.1 - Physician Specimen Drawing, (Rev. 1, 10-01-03).

104. A physician who performs the blood draws on their own patients for blood samples that are then sent to independent laboratories reports the service with HCPCS Code 36415, "collection of venous blood by venipuncture." According to the 2012 Clinical Diagnostic Laboratory Fee Schedule for Medicare, the fee for HCPCS Code 36415 (venipuncture) was $3.00.

b. **Medicare Pays for Blood Draws (Venipuncture) by a Clinical Laboratory**

105. Medicare allows separate charges by laboratories for drawing blood, whether or not the blood is referred to a hospital or independent laboratory. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2 - Independent Laboratory Specimen Drawing (Rev. 1, 10-01-03). In 2012, the service code and payment for specimen collection by a laboratory was also HCPCS 36415.

106. Medicare does not pay the collection ("blood draw") fee to anyone who has not actually extracted the specimen. In addition, only one collection fee is allowed for each type of specimen per patient encounter, regardless of the number of specimens (*i.e.*, vials of blood) drawn. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.

107. Medicare does not pay for routine handling of blood samples referred by one

laboratory to another. *See* Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2 – Independent Laboratory Specimen Drawing (Rev. 1, 10-01-03).

B. **The Medicaid Program**

108. Medicaid is the state-federal funded program for low income children and families, the elderly and people with severe disabilities. Congress created Medicaid in 1965, at the same time as Medicare, when Title XIX was added to the Social Security Act.

109. Medicaid is the largest source of funding for medical and health-related services for America's poorest people.

110. Medicaid is a cooperative federal-state public assistance program which is administered by the states. The Centers for Medicare and Medicaid Services ("CMS") is the federal agency that administers the Medicaid program, and requires all states to provide certain mandatory services. However, because states must also provide funding for their Medicaid program, each state chooses several optional services they wish to provide in addition to the mandatory Medicaid services.

111. Funding for Medicaid is shared between the Federal Government and those state Governments that choose to participate in the program. Federal support for Medicaid is substantial, often exceeding 50% of state Medicaid program funding. For example, in 2012, the federal government provided approximately 65.51% of the funding for North Carolina Medicaid. That same year, the federal government provided 70.43% of the funding for Medicaid programs in South Carolina. The remaining funds were provided by the state governments.

112. Title XIX of the Social Security Act allows considerable flexibility within the States' Medicaid plans and, therefore, specific Medicaid coverage and eligibility guidelines vary by state.

1. Medicaid Programs Pay for Necessary Clinical Laboratory Testing

113. Like the Medicare Program, Medicaid only covers health services or supplies, including laboratory testing, that are necessary for the diagnosis or treatment of a medical condition, in keeping with the standards of good medical practice in the local area. While Medicaid reimbursement for laboratory testing varies by state, there is generally a requirement that the testing is medically necessary.

114. For example, the North Carolina Medicaid program covers only laboratory testing that is medically necessary. North Carolina Medicaid defines "medically necessary" as: "the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs." NC Division of Medical Assistance, Laboratory Services, Medicaid and Health Choice Clinical Coverage Policy 1S-3, Section 3.1.

115. South Carolina Medicaid also covers laboratory testing only if it is "medically necessary for the appropriate care of the patient." South Carolina Health and Human Services Physicians Provider Manual, Section 2, p. 190.

2. Medicaid Coverage for Blood Draws (Venipuncture)

116. Like Medicare, state Medicaid programs also permit a physician to bill for venipuncture when the physician's office actually draws blood samples to be sent to independent clinical laboratories for testing.

117. For example, North Carolina Medicaid reimburses physicians who actually perform blood draws for samples, and, without performing any testing, sends them to non-related outside clinical laboratories. North Carolina Medicaid added CPT procedure code 36415 (collection of venous blood by venipuncture) as a covered service as of January 1, 2005, and since then, North Carolina Medicaid providers have been required to use Code 36415 when

billing for blood draws. *See* Collection of Specimens, October 2012 Medicaid Bulletin, NC Division of Medical Assistance. http://www.ncdhhs.gov/dma/bulletin/1012bulletin.htm#cpt.

118. North Carolina Medicaid covers only one collection fee per beneficiary regardless of the number of specimens drawn. *See* Collection of Specimens, October 2012 Medicaid Bulletin, NC Division of Medical Assistance. http://www.ncdhhs.gov/dma/bulletin/1012bulletin.htm#cpt.

119. North Carolina Medicaid specifically excludes coverage for handling and shipment of specimens. NC Division of Medical Assistance, Laboratory Services, Medicaid and Health Choice Clinical Coverage Policy 1S-3, Section 4.2.

120. South Carolina Medicaid also allows for physicians who perform blood draws to charge Medicaid using Code 36415. The physician or clinic provider may charge the draw fee regardless whether he performs the testing. However, a physician may not bill for a blood draw alone and also bill for an office visit or lab test on the same date. See South Carolina Health and Human Services Physicians Provider Manual, Section 2, p. 191.

C. Other Government-Funded Health Care Programs Pay for Laboratory Tests

1. TRICARE/CHAMPUS and other Federal Healthcare Benefits

121. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of laboratory testing services under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program ("FEHBP").

122. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. It offers military families a choice of three options: TRICARE Prime, TRICARE Extra, and

TRICARE Standard (formerly known as CHAMPUS (Civilian Health & Medical Program for Uniformed Services), a health care plan for military dependents and retirees operated by the DoD.

123. CHAMPVA, administered by the United States Department of Veteran Affairs, is a health care program for the families of veterans with a 100 percent service-connected disability.

124. The FEHBP, administered by the United States Office of Personnel Management, provides health insurance for hundreds of thousands of federal employees, retirees, and survivors.

125. Like Medicare, TRICARE and other federal healthcare benefit programs cover only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (duration or intensity) the level of care, which is needed to provide safe, adequate and appropriate diagnosis and treatments. *See* http://www.usfhp.net/pdfs/Member_Handbook.pdf.

126. TRICARE always requires a referral and/or prescription from the member's primary care physician (PCP) for treatment, including laboratory tests.

2. **Other State-Funded Healthcare Programs**

127. In addition, the named states fund various state-sponsored healthcare programs which cover laboratory testing. These include state employees' healthcare benefits. For example, Dr. Miller's patients who have been referred to Defendants HDL and Singulex include beneficiaries of the South Carolina employees' healthcare program.

3. Private Insurance Pays for Medically Necessary Laboratory Tests

128. Private insurance plans also pay for laboratory testing provided by Defendants HDL and Singulex. Upon information and belief, the contracts for those private insurers whose patients are drawn into the Defendants' referral scheme mirror the Medicare and Medicaid requirements by mandating that laboratory testing billed to private insurers is not the result of an illegal inducement, and is medically necessary.

VI. THE APPLICABLE LAW

A. The Federal False Claims Act – Overview

129. Title 31 USCA Section 3729 of the Federal False Claims Act provides as follows:

> "(a) Liability for Certain Acts -
> (1) IN GENERAL - Subject to paragraph (2), any person who -
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
> (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the

amount of damages which the Government sustains because of the act of that person.

B. **The Federal Anti-Kickback Statute**

130. Enacted in 1972, the federal Anti-Kickback Statute, 42 U.S.C. § 13207b(b), protects patients and federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on healthcare decisions. When a company pays kickbacks to a doctor in order to induce him/her to use the company's products or services, it fundamentally compromises the integrity of the doctor-patient relationship. Government-funded healthcare programs, such as Medicare and Medicaid, rely upon physicians to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by such healthcare program.

131. The federal Anti-Kickback Statute makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person: (1) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or (2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) and (2).

132. A violation of the federal Anti-Kickback Statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Any party convicted under the federal Anti-Kickback Statute must be excluded (*i.e.*, not allowed to bill for any services rendered) from Federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1).

133. The term "remuneration" encompasses anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. 42 U.S.C. § 1320a-7b(b)(1).

134. The Anti-Kickback Statute has been interpreted by the majority of federal courts to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) (holding that the Anti-kickback statute is violated if "one purpose of the payment was to induce future referrals ... even if the payments were also intended to compensate for professional services."); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (adopting the holding in *Greber*); *see also Feldstein v. Nash Community Health Services*, 51 F.Supp.2d 673 (E.D.N.C. 1999)(recognizing that the Medicare fraud statute is violated if "one purpose of the payment was to induce future referrals," and citing *Kats* and *Greber*).

135. Proof of an explicit quid pro quo is not required to show a violation of the Anti-Kickback Statute.

136. The United States Department of Health & Human Services ("HHS") has published "safe harbor" regulations that define practices not subject to the Anti-Kickback Statute because such practices are unlikely to result in fraud or abuse. 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. As further explained herein, none of the practices at issue in this *Qui Tam* Complaint meet these safe harbor regulations.

137. Compliance with the Anti-Kickback Statute is a *condition of payment* under Government healthcare programs, including the Medicare and Medicaid programs, and that condition applies regardless of whether the kickback payor or recipient is submitting the claim to the Government. Claims that arise from a kickback scheme are per se false, and violate the False

Claims Act, because they are the result of a kickback – no further express or implied false statement is required to render such infected or tainted claims false, and none can wash the claim clean.

138. On March 23, 2010, as part of the Patient Protection and Affordable Care Act, PL 111-148 ("PPACA"), the Anti-Kickback Statute was amended to explicitly provide that a claim resulting from a violation of the Anti-Kickback Statute is a violation of the federal False Claims Act. Specifically, the federal AKS was amended by adding subsection (g) to 42 U.S.C. § 1320a–7b. 42 U.S.C. 1320a–7b(g), which states that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code."

139. In addition, Section 6402(a) of the PPACA established section 1128J(d) in the Social Security Act regarding reporting and returning Medicare and Medicaid overpayments. Section 1128J(a) requires a person who has received an overpayment to report and return the overpayment by the later of (i) 60 days after the overpayment was identified or (ii) the date any corresponding cost report is due. The knowing and improper failure to return an overpayment subjects the recipient to liability under the federal False Claims Act, 31 U.S.C. § 3730(a)(1)(G).

1. HHS-OIG: Fraud Alert on Lab Services and Tainted Referrals

140. The Office of Inspector General (OIG) has issued fraud alerts on clinical laboratory services. OIG has noted that "[m]any physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Since the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician's decision regarding where to refer specimens is based only on the best interests of the

patient." OIG Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

141. OIG has stated that "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." OIG Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

142. Likewise, "whenever a referral source solicits or receives anything of value from the laboratory," the same inference (that the thing of value is offered to induce the referral of business) may be made. By ``fair market value'' OIG means "value for general commercial purposes," which "must reflect an arm's length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them." OIG Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

143. OIG has issued a Special Fraud Alert regarding kickbacks associated with a lab that provides phlebotomy services to referring physicians. In particular, OIG has noted:

- When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory.
- While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks

that are normally the responsibility of the physician's office staff;

- In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute.

OIG Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Issued October 1994).

144. As described below, under compensation arrangements between HDL and Singulex, referring physicians receive "processing" fees from HDL and Singulex.

C. State False Claims Acts ("State FCAs")

145. The false claims acts of the sovereign States of North Carolina, California and Illinois generally mirror the federal FCA. Thus, the state FCAs at issue impose liability on a person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- conspires to commit a violation of the false claims act; or
- knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

146. The false claims acts of the States of North Carolina, California and Illinois each provide for liability to the state for a civil penalty plus damages. Most of the relevant state FCAs provide for the Defendants to pay three (3) times the amount of damages which the State sustains because of the FCA violation.

147. California, Illinois, and North Carolina also have anti-kickback laws. *See e.g.*, Cal. Wel. & Inst. Code § 14107.2 (prohibiting kickbacks) and § 14107.11 (payments to providers to be suspended upon credible allegations of fraud); 89 Ill. Adm. Code 140.35 (subjecting Medicaid providers to federal and state anti-kickback law); N.C. Gen. Stat. § 90-401 (prohibiting the payment or receipt of kickbacks). Thus, California, Illinois, and North Carolina prohibit coverage by their State healthcare programs for claims tainted by illegal inducements.

148. Both California and Illinois have *qui tam* statutes that permit relators to raise allegations of fraud by individuals or entities against private insurance companies. The statutes operate similarly to the federal and state FCAs, and are written to prevent fraud occurring in the private health care insurance market.

149. Upon information and belief, Singulex and HDL receives significant revenues from private insurers in California and Illinois.

150. Upon information and belief, Defendants Singulex and HDL are paid by private insurers that cover California- and Illinois-based patients who have been referred for testing as a result of Defendants' scheme.

151. Upon information and belief, private healthcare insurance companies in California and Illinois require the same conditions of payment and prohibitions on unnecessary medical testing found in the Medicare and Medicaid programs.

152. The CIFPA prohibits as unlawful the following:

> It is unlawful to knowingly employ runners, cappers, steerers, or other persons…to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer.

Ca. Ins. Code § 1871.7(a). Any person or entity found in violation of this section or specifically identified corollary criminal code sections is subject to civil penalties ranging from $5,000.00 to

$10,000.00 per false claim plus three times the amount of each false claim for compensation from an insurer. Cal. Ins. Code § 1871.7(b).

153. Under the CIFPA, any interested person may bring a sealed civil action for a violation of Section 187.7 on behalf of the State of California. Ca. Ins. Code § 1871.7(e)(1), (2). If the relator is ultimately successful and the District Attorney intervenes in the lawsuit, the relator is entitled to the recovery of fees, expenses, and a relator's share of between 30% and 40% according to the priority specified in the statute. Cal. Ins. Code § 1871.7(g)(1)(A)(iii)(I), (IV). If neither the District Attorney nor the Insurance Commissioner intervene and the relator is successful in settling his/her lawsuit or attaining final judgment, the relator may receive between 40% and 50% of the proceeds plus costs and expenses. Cal. Ins. Code § 1871.7(g)(2)(A).

154. The Illinois Insurance Claims Fraud Prevention Act ("ILCFPA") is similar to the CIFPA. In Section 92/5(a), the ILCFPA prohibits kickbacks and states:

> ...[I]t is unlawful to knowingly offer or pay any remuneration directly or indirectly, in case or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer.

740 Ill. Comp. Stat. § 92/5(a). If a defendant is in violation of Section 92/5(a) or specifically identified corollary criminal code sections, he/she must reimburse three times the amount of money defrauded as well as civil penalties ranging from $5,000.00 to $10,000.00 per fraudulent claim. 740 Ill. Comp. Stat. § 92/5(b).

155. Pursuant to Section 15 of the ILCFPA Section 15, an interested person may bring a sealed civil action for a violation of the ILCFPA on behalf of him/herself and the State of Illinois. 740 Ill. Comp. Stat. § 92/15(a), (b). If the State's Attorney and/or the Attorney General intervene in the *qui tam* action, and it is ultimately successful, the relator is entitled to at least

30% of the recovery. 740 Ill. Comp. State § 92/25(a). If neither government entity intervenes and the relator successfully pursues the lawsuit on his/her own, the relator is entitled to recover not less than 40% of the proceeds. 740 Ill. Comp. Stat. § 92/25(b).

156. Relators here are the original sources of the allegations under the CIFPA and ILCFPA.

VII. ALLEGATIONS: DEFENDANTS HDL AND SINGULEX PROVIDE INDUCEMENTS FOR PATIENT REFERRALS FOR LABORATORY TESTS

A. Overview of HDL, Singulex, and BlueWave's Operations

1. The Berkeley Connection to HDL, BlueWave, and Singulex

157. Defendant HDL's founder, Defendant Mallory, was a former employee of Berkeley HeartLab ("Berkeley"), a clinical laboratory which provides testing related to coronary disease. At Berkeley, Ms. Mallory was Senior Manager, Lab Operations from February 2006 to 2008. During that time, she led tremendous growth through new business initiatives. Mallory resigned from Berkeley in September 2008, and incorporated HDL that November.

158. Defendant HDL began operations in June 2009; and started processing blood samples in November 2009.

159. Defendant BlueWave also has connections to Berkeley. For example, Defendant BlueWave founder, Defendant Dent, and BlueWave's sales representative, Carnaggio, were leading marketing representatives for Berkeley until late 2009.

160. Carnaggio and Defendant Dent worked for Berkeley as a sales team promoting clinical laboratory testing for the diagnosis and treatment of high cholesterol and cardiovascular disease. Their sales territory included parts of North Carolina, South Carolina, and Georgia. Dr. Miller's office was in Dent's and Carnaggio's territory.

161. Like Dent, Defendant Johnson, the other BlueWave co-founder, also worked at Berkeley until late 2009. While there, Johnson was Berkeley's primary sales representative for Alabama, Mississippi, and part of Florida.

162. The business name "BlueWave Healthcare Consultants, Inc.," was reserved on October 28, 2009, only two months before Dent and Johnson left Berkeley.

163. Carnaggio, Dent, and Johnson, were among the Berkeley sales representatives who resigned simultaneously on January 1, 2010. Dent and Johnson incorporated BlueWave on January 4, 2010. Carnaggio, Dent, and Johnson immediately became part of the original BlueWave sales team.

164. BlueWave has been the near-exclusive marketing agent for HDL since at least January 2010. In fact, BlueWave is identified as a "strategic partner" on Defendant HDL's website.

165. Several months after incorporating BlueWave, in June 2010, Defendant BlueWave became the exclusive marketing agent for Defendant Singulex. Defendant Johnson, a BlueWave co-owner, is also an equity owner in Singulex.

166. Upon information and belief, the fraud alleged here, to pay physicians bogus processing fees, was part of Defendant HDL's (and BlueWave's) strategy to lure physician customers from Berkeley to HDL, and eventually to Defendant Singulex.

2. BlueWave's Operations: Sales Force for HDL and Singulex

167. Neither Defendant HDL nor Defendant Singulex employs its own outside sales force. Instead, Defendant BlueWave serves as the marketing agent for Defendants HDL and Singulex. BlueWave sales representatives promote Singulex and HDL products to physicians and physician practices throughout the country.

168. On or about June 1, 2010, Defendant BlueWave signed an agreement with Defendant Singulex for the exclusive right to promote Singulex testing services to physicians in certain sales territories. The BlueWave sales territories for Singulex have since expanded.

169. The BlueWave-Singulex marketing agreement mandates that Singulex pay physicians and independent lab companies for processing and handling of blood samples.

170. Relators allege, upon information and belief, that sometime before January 1, 2010, the principals of Defendant BlueWave also entered into an agreement with HDL for the near-exclusive right to promote HDL products to physicians across the United States, which was similar to the agreement between Singulex and BlueWave. Relators further allege upon information and belief, and therefore aver, that Defendant HDL is similarly required to pay physicians and independent lab companies for processing and handling fees for HDL tests.

171. Defendant BlueWave, through its representatives, including Carnaggio and Defendant Dent, also provides on-going customer service for Defendants HDL and Singulex. These customer service activities include providing marketing information about HDL and Singulex services, coordinating the delivery of HDL supplies to facilitate referrals, and facilitating payments of processing fees to referring physicians. For example, Carnaggio recently corrected an issue with Singulex payments to Dr. Miller.

B. Relators Discover HDL and Singulex Payments to Dr. Miller for Referrals

172. As stated above, Relator Webster has been a registered nurse for Dr. Miller's practice since May 2008. Relator Lutz was contracted in early 2011 to assist Dr. Miller with billing. Relators have obtained knowledge and information that Defendants participate in a scheme to fraudulently induce Dr. Miller and other physicians to refer thousands of patients for testing that is not reimbursable by Government healthcare programs.

1. **Lloyd Miller, MD.**

173. Lloyd Miller Jr., MD is a primary-care physician licensed to practice in the state of South Carolina.

174. Since September of 2011, Dr. Miller has done business as Internal Medicine of Carolinas (owned by Carolinas Medical Alliance), 2501 S. Vance Drive, Suite B, Florence, SC 29505. Before that time, Dr. Miller did business as Internal Medicine Associates, PC, with an office located at 805 Pamlico Hwy, Suite B 310, Florence, SC 29505. Internal Medicine Associates is also the alter ego of Lloyd Miller, MD.

175. LCM Enterprises of Florence, Inc. ("LCM"), is a South Carolina corporation formed in 1991 by Lloyd Miller, MD, whose principal place of business is located at 2501 South Vance Drive, Suite B, Florence, SC 29505. LCM is also the alter ego of Lloyd Miller, MD.

176. Dr. Miller's staff has included, but is not limited to, the following current employees: Ginger Tolson, Office Manager; Relator, Kayla Webster, RN, Nursing Supervisor; and office assistants Mandy Floyd and Kandice Smith. Dr. Miller does not employ a phlebotomist to draw blood for patients' laboratory tests.

C. **BlueWave & HDL Lure Physicians with "Processing" Fees**

1. **BlueWave and HDL Redirect Dr. Miller's Referrals to HDL**

177. Beginning in late 2009 or early 2010, BlueWave marketing agents began promoting HDL testing services. Immediately, Dr. Miller stopped referring patients to Berkeley and began referring his patients to Defendant HDL.

a. **"Berkley" is Pre-Printed on His Encounter Page**

178. Before they began marketing Defendant HDL clinical laboratory testing services, BlueWave's sales representatives (Carnaggio and Dent) marketed Berkeley tests related to coronary disease to Dr. Miller. In fact, Dr. Miller referred patients to Berkeley so often that the

Berkeley (misspelled "Berkley") test was added to Dr. Miller's pre-printed patient encounter sheet.

179. Dr. Miller ordered Berkeley tests for nearly every patient in his robust practice.

b. After Dr. Miller Abruptly Shifts to HDL, "Berkeley" Means "HDL"

180. Relator Webster observed Dr. Miller abruptly stop referring patients to Berkeley on or about January 1, 2010. Dr. Miller immediately began referring all, or nearly all, patients to Defendant HDL.

181. Although BlueWave was not formally incorporated until January 4, 2010, based on the reservation of the "BlueWave" name during late 2009, and the immediate change in Dr. Miller's referrals to HDL very early in January, 2010, Relators believe that BlueWave's founders had initiated promotion of HDL testing services to physicians (including Dr. Miller) in late 2009.

182. Soon after shifting patient referrals to Defendant HDL, Dr. Miller started receiving monthly payments from HDL that were calculated at $20 for per patient listed on a "draw log" which accompanied the check from HDL to Dr. Miller. Upon information and belief, BlueWave, through Carnaggio and Defendant Dent, offered HDL's inducements, at the direction of Defendant Mallory, to Dr. Miller.

183. HDL maintained the "draw log," which listed each patient referred to Defendant HDL. One purpose of the monthly payments by HDL to Dr. Miller was to induce him to refer patients to HDL.

184. While Dr. Miller almost immediately changed his referrals from Berkeley to HDL, he did not immediately change his pre-printed patient encounter form. After January 1, 2010, when a patient's encounter form was marked "Berkley," this meant that the patient was referred to Defendant HDL for testing.

185. In addition to paying the $20.00 fee for every patient listed on the "draw log," to facilitate the referrals for testing, Defendant HDL provided Dr. Miller with pre-printed laboratory requisition forms, all of the necessary collection, and shipping supplies (blood collection tubes, bags, ice packs, shipping boxes and pre-paid FedEx labels). Dr. Miller's office ordered these supplies, as needed, by sending a request to Defendant HDL via facsimile.

186. Dr. Miller's staff does not use the blood draw "kits" provided by HDL. When Dr. Miller's staff receives the HDL blood draw supplies, they provide these to the phlebotomist provided by Laboratory Corporation of American ("LabCorp"). The LabCorp technician stores the HDL blood draw supplies, draws blood samples for HDL testing, and processes the samples for HDL.

2. HDL Pays Referring Physicians, Including Dr. Miller, Bogus "Processing" Fees

187. As stated above, in March of 2011, Relator Lutz began to provide billing services for Dr. Miller. After March 2011, but before September 2011, in approximately August 2011, someone left an unmarked envelope at Relator Lutz's office. When Ms. Lutz opened the envelope, it contained copies of payment checks from Defendants HDL and Singulex to Dr. Miller or his companies for bogus "processing fees." It also contained copies of "draw logs," lists of patients referred by Dr. Miller to HDL and Singulex in support of each payment.

188. Defendant HDL pays Dr. Miller $20.00 for each patient referred to HDL for laboratory testing.

189. When Relator Lutz closely examined the documents related to Defendant HDL's payments to Dr. Miller, she noted the following:

- From January 2010 through the end of 2012, Relators estimate that Defendant HDL paid Dr. Miller $133,300 for referrals of approximately 6,665 patients, or between 150 and 185 patients per month.
- Estimated conservatively, 47 percent of the patients referred by Dr. Miller to HDL were beneficiaries of Government Healthcare programs.

190. HDL kickback checks may be made payable to the physician, the physician's practice, or a related corporate entity. For example, Defendant HDL has made payments to Dr. Miller through checks made payable to "Internal Medicine Associates, P.C.," which were signed by its President, CEO, and founder, Tonya Mallory.

191. Defendant HDL's practice of offering and paying a $20.00 per patient inducement to referring physicians, including Dr. Miller, continues today.

3. HDL "Processing" Arrangements with Physicians, Including Dr. Miller, Are Bogus

192. In literature provided to physician customers, Defendant HDL describes the many steps it considers part of the processing services that are the responsibility of referring physicians (after the blood draw), including the following:

- Immediately invert 8-10 times after blood draw;
- Allow to clot for 30 minutes in an upright position;
- Centrifuge for 15 minutes at 3000 rpm;
- Place tube in the biohazard bag provided with absorbent material;
- Place in refrigerator until ready for shipment;
- Place specimen(s) inside biohazard bag with absorbent pad;
- Complete required information on the requisition form;
- Place test requisition in the outside pouch of the biohazard bag;

- Place a frozen cool-pack brick in the bottom of Styrofoam cooler;
- Place three to four paper towels (for insulation) over the brick;
- Insert the refrigerated specimen bags in the Styrofoam cooler;
- Place two paper towels over the refrigerated specimens;
- Immediately replace the Styrofoam cooler lid before closing the box.

193. HDL pays referring physicians under arrangements purporting to compensate physicians for "processing" blood samples for HDL tests.

194. Relators allege upon information and belief, that Defendant HDL enters into bogus service arrangements with referring physicians in an attempt to disguise HDL's inducements for referrals as market-value compensation for bona fide professional services.

195. In contrast to HDL's product literature, Relator Webster has observed that HDL's referring physician, Dr. Miller, does not provide any substantive blood sample processing services. Rather, the lab technician provided to Dr. Miller's office by LabCorp, performs all (or nearly all) of the blood processing services for patients referred to HDL.

196. Dr. Miller's staff performs only minimal processing tasks on HDL blood samples: completing required information on the requisition form; attaching labels to tubes containing blood samples; placing test requisition in the outside pouch of the biohazard bag; placing a frozen cool-pack brick in the bottom of Styrofoam cooler and adding the refrigerated specimen bags; replacing the cooler lid; and closing the box.

197. The LabCorp technician assigned to Dr. Miller's office performs all of the HDL blood draws, as well as most of the HDL processing tasks: immediately invert 8-10 times after blood draw; allow to clot for 30 minutes in an upright position; centrifuge for 15 minutes at 3000

rpm; place tube in the biohazard bag provided with absorbent material; and place in refrigerator until ready for shipment.

198. Even if the blood processing services were performed by Dr. Miller or his staff, the $20.00 payment by Defendant HDL exceeds fair market value, and the total compensation to Dr. Miller is directly related to the number (volume) of his patient referrals.

199. Nonetheless, and without regard to the fair market value of Dr. Miller's services, Defendant HDL pays Dr. Miller the $20.00 to perform minimal services on blood that is drawn and largely processed by LabCorp.

4. Defendant Singulex's Inducements: $10 Per Referral Are Bogus "Processing" Fees

200. Defendant BlueWave became the exclusive marketing agent for Defendant Singulex in June 2010. About that same time, BlueWave, through its marketing agents, began promoting Singulex testing services to physicians in their sales territory, including Dr. Miller.

201. As stated above, when BlueWave's sales representatives (Carnaggio and Dent) marketed Berkeley clinical laboratory tests related to coronary disease, Dr. Miller had the "Berkley" ("B") test added to his patient encounter sheet, but he did not immediately change his pre-printed patient encounter form. Thus after January 1, 2010, when a patient was referred to HDL, the encounter form box next to "Berkley" was selected.

202. When Defendants BlueWave, Dent, and Johnson started marketing Singulex testing with HDL, Dr. Miller began referring patients to both HDL and Singulex. For example, Dr. Miller would note on the patient encounter sheet that the patient should have "Berkley/Singulex," or "B/S" testing when he was referring patients to Defendant HDL and Defendant Singulex.

203. During June or July 2010, Dr. Miller began to refer all of his patients for testing by both Singulex and HDL. Soon thereafter, Dr. Miller began to receive payments from Defendant Singulex of $10.00 per patient referral, in addition to the payment of $20.00 per patient referral that he received from Defendant HDL. Thus, for patients referred to both HDL and Singulex, Dr. Miller received $30.00 each time the patient was tested. Like the HDL payments, one purpose of the payments by Defendant Singulex was to induce Dr. Miller to refer patients to Singulex for testing.

204. When Relator Lutz examined the documents related to Defendant Singulex's payments to referring physician Miller, she noted the following:

- From July 2010 through the end of 2012, Defendant Singulex paid Dr. Miller an estimated $55,540 for referrals of approximately 5,554 patients, or between 150 and 185 patient referrals per month.
- Conservatively, 47 percent of the patients referred were beneficiaries of Government Healthcare programs.

205. Defendant Singulex's practice of offering and paying a $10.00 per patient inducement to referring physicians, including Dr. Miller, continues to today. The Singulex checks to Dr. Miller were signed by **REDACTED**

206. HDL and Singulex kickback checks may be made payable to the physician, the physician's practice, or a related corporate entity. For example, Defendants HDL and Singulex have a compensation arrangement with Dr. Miller, under which HDL and Singulex have made payments to various entities associated with Dr. Miller. Both Defendants HDL and Singulex have made payments to Dr. Miller through checks made payable to "Internal Medicine

Associates, P.C." Defendant Singulex has also made payments to Dr. Miller through checks made payable to "LCM Enterprises of Florence, Inc."

207. The named parties to the Singulex process and handling "Agreement for Singulex Clinical Lab Cardiovascular Testing" are Singulex and "LCM," Dr. Miller's alter ego. Singulex's former CEO, Defendant Goix, signed the processing and handling agreement on behalf of Defendant Singulex.

5. **Singulex "Processing Services" Agreements Are False Records**

208. Defendant Singulex has entered into a sham agreement with Dr. Miller titled "Agreement for Singulex Clinical Lab Cardiovascular Testing." In the agreement, Singulex states that the physician, Dr. Miller, is paid the $10.00 fee to perform the following "processing services:"

- The phlebotomy draw;
- Allocation of specimens into multiple vials as defined in the Singulex Specimen Collection Instructions;
- Assignment of labels to the vials;
- Packing of specimens into the Singulex shipping kits provided to the practice;
- Labeling of the shipment package; and
- Scheduling of shipment pickup.

209. Defendant Singulex also has literature which describes the tasks it considers part of the processing services to be performed by physicians who refer patients to Singulex for laboratory testing:

- Invert 4-5 times;
- Centrifuge for 15 minutes at 3000 RPM;

- Refrigerate;
- Place tube into front pouch of Specimen Transport Bag;
- Fold and place copies of completed requisition form and demographic sheet into back pouch of Specimen Transport Bag;
- Pack shipment box in order shown, with Specimen Transport Bags sandwiched between refrigerant gel;
- Affix Singulex FedEx Airbill.

210. Relator Webster has observed that Dr. Miller does not perform or pay for (by having his staff perform them) processing services for Singulex blood samples as described as physician responsibilities in the "Agreement for Singulex Clinical Lab Cardiovascular Testing". Since approximately spring of 2011, LabCorp has provided all of the blood draw services, and virtually all of the processing services for tests on patients referred by Dr. Miller to Defendant Singulex.

211. Dr. Miller's staff has minimal involvement in handling Singulex blood samples: assignment of labels to the vials; packing of specimens into the Singulex shipping kits provided to the practice; fold and place copies of completed requisition form and demographic sheet into back pouch of Specimen Transport Bag; and place the blood samples in Singulex's shipment box. It is not necessary for Dr. Miller to label the shipment package because Singulex provides prepaid, labeled FedEx boxes. In addition, the Singulex packages are picked up daily, so there is no need to schedule the pickup.

212. The LabCorp representative performs most of the blood processing tasks listed as Dr. Miller's responsibilities in the "Agreement for Singulex Clinical Lab Cardiovascular Testing" and described in Singulex's processing instructions for referring physicians: the

phlebotomy draw; allocation of specimens into multiple vials per Singulex Specimen Collection Instructions; invert 4-5 times; centrifuge for 15 minutes at 3000 RPM; place tube into front pouch of Specimen Transport Bag; and refrigerate.

213. In contrast to the Singulex processing agreement and product literature, Dr. Miller receives Singulex's $10.00 fee per patient referral, but neither he nor his staff performs substantive blood processing services. Rather, the LabCorp technician in Dr. Miller's office performs the majority nearly all of the processing services on blood samples referred to Singulex.

6. CMS Pays for Blood Draws, But Not "Processing" Services

214. Government healthcare programs, such as Medicare and Medicaid, reimburse physicians or laboratories only if their staff actually performs the blood draw (venipuncture). Thus, if Dr. Miller actually preformed the blood draw, his fee would be $3.00. Because Dr. Miller does not perform the phlebotomy draw for HDL and Singulex tests, he is not entitled to a fee for blood collection.

215. Likewise, an independent laboratory, such as LabCorp may bill for the venipuncture (blood draws) performed for Dr. Miller's patients. Even then, the Medicare reimbursement for LabCorp would be $3.00, which is significantly less than the $20.00 HDL pays physicians for minimum "processing" services.

216. Where LabCorp performs the blood draw, only it may bill Government healthcare programs, including Medicare, for the venipuncture (blood draws). LabCorp would receive only one blood draw fee of $3.00, even though it draws samples for LabCorp, HDL, and Singulex from a given patient.

217. Government healthcare programs such as Medicare do not reimburse physicians or laboratories for "processing" services for blood samples sent to laboratories. Where one

laboratory (LabCorp) draws blood for another laboratory (HDL or Singulex), routine processing (handling) charges are not reimbursable services under Government healthcare programs. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2.

218. LabCorp provides both blood draws and blood processing services for Dr. Miller's patients referred to HDL for testing. Medicare does not reimburse LabCorp for "processing" services on blood samples sent to HDL. Relators do not believe that Dr. Miller or Defendant HDL pays LabCorp to perform the "processing" services.

219. Instead, LabCorp performs the majority of processing services for HDL samples, but HDL pays the $20.00 per patient "processing" fee directly to the referring physician, Dr. Miller.

220. Singulex pays draw fees to referring physicians who do not perform the venipuncture. The Singulex agreement states that Dr. Miller or his staff is supposed to perform both the blood draw and the blood processing services in exchange for the $10.00 processing fee. LabCorp, not Dr. Miller, performs the blood draw services. Thus, Dr. Miller is not entitled to the portion of the Singulex fee for the blood collection.

221. Similarly, Government healthcare programs reimburse physicians only if their staff actually performs the blood draw (venipuncture). Even then, the Medicare reimbursement is $3.00, which is less than one third of the $10.00 payment by Singulex to Dr. Miller.

222. Even if Dr. Miller's staff did perform the blood processing services for patients referred to Singulex, the $10.00 payment by Defendant Singulex far exceeds fair market value for these services. The Singulex payments are also directly related to patient referrals.

223. Medicare does not pay for routine handling charges where a specimen is referred by one laboratory to another. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2 - Independent Laboratory Specimen Drawing, (Rev. 1, 10-01-03).

224. Government healthcare programs do not reimburse for services such as refrigeration, processing, and shipping which have only minimal value.

225. Defendant Singulex's practice of offering and paying Dr. Miller an inducement of $10.00 per patient referral continues today.

7. **HDL and Singulex Arrangements with Dr. Miller Violate AKS**

226. Defendants fail to meet any of the Safe Harbors to the AKS.

227. Defendants do not meet the requirements of the personal services exception to the AKS, 42 CFR § 1001.952 (d), which requires that Defendants HDL and Singulex meet all seven of the following elements:

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a fulltime basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the

volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

228. The arrangements between HDL, Singulex, and Dr. Miller fail at least two of the requirements of 42 C.F.R. § 1001.952 (d)(5). Payments by HDL and Singulex far exceed fair market value. In addition, payments by HDL and Singulex are "determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."

229. Defendants HDL and Singulex keep careful records of both the patients referred and the inducements paid to each physician, including Dr. Miller. Under the guise of "processing fees" paid in exchange for the referrals, Defendant HDL and Defendant Singulex continue to violate federal and state anti-kickback laws by paying physicians, including Dr. Miller, for patient referrals.

D. HDL and Singulex Inducements Lead to Referrals for Unnecessary Testing

230. Defendants' inducements lead to excessive and unnecessary testing that does not benefit patients and is of no diagnostic value.

231. Defendants HDL and Singulex initiated the fraudulent lab testing scheme by incentivizing Dr. Miller and other physicians with cash payments that induced them to order HDL and Singulex tests for their patients. The monetary inducements offered by HDL and Singulex, not medical necessity or the appropriateness of testing providers, guide the physician's referral.

1. HDL and Berkeley Are Not Interchangeable Products: the Type of Patients Referred to Berkeley Would Not Benefit from HDL Testing

232. Until late 2009, Dr. Miller was one of Berkeley's most valued customers.

233. HDL, through Defendant Mallory its founder, president, and CEO, has stated that Berkeley testing and HDL testing serve different medical purposes: the Berkeley tests are aimed at trying to help people who have already had a heart attack stop the second one; while the HDL tests are used to prevent the first heart attack.

234. Despite the very different medical purposes served by HDL's tests, and HDL's position that a patient who is referred to Berkeley (patient who already had a heart attack) would not benefit medically from HDL testing (trying to prevent first heart attack), Defendant HDL, through its marketing agents (Defendant BlueWave's sales representative, including Defendant Dent) abruptly shifted many physicians referrals from Berkeley testing to HDL testing in early 2010.

235. For example, Dr. Miller abruptly stopped referring patients to Berkeley on or about January 1, 2010. He immediately began referring nearly all of his patients to Defendant HDL.

236. DDF, a patient of Dr. Miller's with Medicare insurance, was referred for Berkeley testing on December 10, 2009. The next time he returned to Dr. Miller's office, on March 4, 2010, DDF was referred for HDL testing. (If Defendant HDL's CEO is correct that a patient

who is referred to Berkeley (already had a heart attack) would not benefit medically from HDL testing (trying to prevent first heart attack), none of the HDL testing performed on the sample drawn from DDF March 4, 2010 was medically necessary.) DDF is one example of the many patients of Dr. Miller who were referred to Berkeley for testing before January 2010, but were referred to HDL after January 2010.

2. **Patients Did Not Suffer From High Cholesterol**

237. To mask the HDL and Singulex testing scheme, Dr. Miller gave all patients referred to HDL and/or Singulex a diagnosis of high cholesterol, even when there was no clinical indication that the patient suffers from high cholesterol.

238. In fact, patient notes often did not include a diagnosis that would support HDL and/or Singulex testing. When this occurred, Dr. Miller's office manager would "find" support or have Dr. Miller add the needed diagnosis to the patient chart.

239. According to Relators' review of patient records and claims for testing, many beneficiaries who were referred by Dr. Miller to Defendants HDL and Singulex had no history of high cholesterol.

240. In many instances, Defendant HDL's and Singulex's laboratory reports for Dr. Miller's patients support the conclusion that HDL and/or Singulex testing was not medically necessary.

241. In addition, underlying documentation for patients referred to Defendants HDL and Singulex often lacked support for the diagnosis of high cholesterol, both at the time they were initially referred to HDL and/or Singulex for testing, and when these labs performed follow-up testing.

242. For example, Relators reviewed many HDL and Singulex lab requisitions for patients referred by Dr. Miller to Defendants HDL and Singulex between January 2010 and

December 2012. Virtually all of these patients were diagnosed as having hypercholesterolemia (high cholesterol), most often documented as ICD-9-CM Code 272.0, "Pure hypercholesterolemia." However, when Relator Webster reviewed the patients' underlying records, high cholesterol was not the primary or even secondary diagnosis for many of these patients. Some of these patients' records did not include a diagnosis of high cholesterol at all.

243. A review of the patient charts and laboratory testing reports issued by Defendants HDL and Singulex reveals that Dr. Miller's patients are subjected to follow-up testing by Defendants HDL and Singulex even after initial testing showed that the patient was within appropriate limits for HDL or at target established by Singulex.

244. For example, the HDL testing showed that the following patients did not have high cholesterol and exhibited few warning signs of cardiovascular disease:

Patient	Sex	Age	Specimen Collected (Referral Date)	HDL Report Date
RW	F	42	11/6/2012	11/7/2012
BB	F	22	11/6/2012	11/7/2012
TW	M	68	6/6/2012	6/7/2012

245. These HDL laboratory testing reports showed that the patients had cholesterol levels which, according to HDL's own standards, were "optimal."

246. Similarly, testing by Defendant Singulex showed some of Dr. Miller's patients were not at risk for cardiovascular disease. Singulex reports showed that these patients were "at target," according to Singulex's own indicators for cardiovascular health.

247. The following patients, including Medicare-age beneficiaries, were referred to Singulex by Dr. Miller after Defendants Singulex began offering Dr. Miller inducements.

However, these patients were neither "at risk" nor at "moderate risk" for Cardiopathology (Cardiac Trononin-I) nor Vascular Inflammation (Interleukin-6 and Interleukin-17A):

Patient	Sex	Age	Specimen Collected (Referral Date)	Singulex Report Date
LB	M	65	11/14/2012	11/20/2012
TLB	M	72	11/15/2012	11/20/2012
LHS	F	69	11/13/2012	11/20/2012
JWE	M	61	11/15/2012	11/20/2012
EAD	M	42	3/6/2012	3/12/2012

248. Dr. Miller's patients who were "at target," according to Singulex's own indicators for Cardiovascular health, were subjected to additional unnecessary follow-up Singulex testing. For example, patient "EAD"—a dual-eligible patient with both Medicare and Medicaid insurance—was "At Target" based on tests by Singulex in August 2011. Nonetheless, Dr. Miller referred EAD to Singulex for Singulex Advanced Panels in November 2011, March 2012 and August 2012. All results on all Singulex tests were "At Target."

249. Similarly, patient TW was referred to Defendant HDL in June 2012, when HDL's report showed that their cholesterol levels, according to HDL's own standards, were "Optimal." Nonetheless, in October 2012, Dr. Miller again referred TW to HDL for the full battery of HDL tests.

250. Although, based on the earlier testing results, these patients need no further testing for high cholesterol, Dr. Miller continued to be induced by HDL's and Singulex's offers of substantial cash payments to repeatedly refer patients to HDL and Singulex.

251. Relators are not aware of any instance where Defendants HDL or Singulex has advised a referring physician to discontinue testing on a patient whose initial testing revealed that the patient was "at target" or "optimal" levels established by Defendants HDL and Singulex.

252. The over-utilization of the expensive HDL and Singulex tests was a natural and foreseeable consequence of the illegal financial inducements HDL and Singulex paid to physicians like Dr. Miller for each patient referred for testing.

3. HDL and Singulex Testing Does Not Affect Therapy or Treatment

253. Most often, Dr. Miller did not review the HDL and Singulex laboratory reports with his patients. Rather, these reports were merely filed in a patient's chart. Only when a patient asked about earlier lab testing would Dr. Miller or a staff member review them.

254. Relators believe that Dr. Miller did not use the Singulex, HDL or LabCorp results as part of medically necessary treatment. The testing performed by HDL and Singulex most often did not result in a change in patients' therapy.

255. Testing services referred to Defendants HDL and Singulex by Dr. Miller did not appear to have been medically necessary for the treatment of an illness or injury in Dr. Miller's patients, including Government healthcare program beneficiaries.

4. Even Though HDL and Singulex Required Fasting for Accuracy, Patients Were Not Instructed to Fast

256. For HDL to provide accurate testing results, patients are required to fast (not eat food) for at least 8-10 hours before their Health Screening in order to obtain accurate test results.

257. Dr. Miller never instructed his patients to fast.

258. When Dr. Miller's patients had fasted for less than 8-10 hours (or when patient fasting was not documented at all), the tests performed by HDL did not meet HDL's own criteria for accuracy.

259. HDL's own documents often show that Dr. Miller's patients had fasted for far less than 8-10 hours. Most often, patient fasting was not documented at all. As a result, the ensuing lab report issued by HDL states "fasting unknown." For example, the HDL requisition for LB dated 12/10/2012 has no information on whether the patient fasted. The HDL lab report dated 12/15/2012 states: "Fasting Status: Unknown."

260. HDL knew that the accuracy of its testing services required that patients fast for 8-10 hours. HDL was able to determine before it conducted the testing on Dr. Miller's patients, based on its own lab requisition form, whether the testing results would be accurate (fasting documented) or inaccurate (fasting not documented). In cases where fasting was not documented, and HDL knew the results would not be accurate, Defendant HDL routinely performed the testing services anyway.

261. HDL knew when it performed laboratory testing services where fasting was not documented that the results would be inaccurate..

262. Defendant Singulex also requires lab technicians to document the patient's fasting hours on the Singulex lab requisition.

263. Records for Singulex, including requisitions and lab reports, show that many of Dr. Miller's patients fasted as little as 3 hours, or not at all. Singulex lab requisitions for Dr. Miller's patients often had blanks next to required fasting information. The related lab report issued by Singulex often states "fasting unknown." For example, the Singulex requisition dated 12/10/2012 for LB had no information next to "# hours since patient last ate." The Singulex lab report for LB dated 12/15/2012 states "# Hours Since Patient Last Ate: Unknown."

264. Defendant Singulex knew before it conducted the testing on Dr. Miller's patients, based on its own lab requisition form, whether the testing results would be accurate (fasting

documented) or inaccurate (fasting not documented). In every case where fasting was not documented, Defendant Singulex still performed the testing services.

265. Singulex knew when it performed laboratory testing service that the results would be inaccurate.

266. In addition, Defendant HDL's and/or Singulex's faulty testing and related inaccurate laboratory reports provided to physicians could lead to unnecessary treatments or inaccurate diagnoses. For example, patients who did not fast for a glucose/insulin test may be misdiagnosed with Type II diabetes, which is indicated by high glucose/insulin levels.

5. Nearly Blank Requisitions For HDL and Singulex Testing Are Not Valid Referrals

267. A patient referral for laboratory testing must include a diagnosis and must detail the services to be performed. 42 C.F.R. § 410.33(d). Otherwise, the laboratory cannot show accurate processing of the physician's order, nor can it demonstrate that the service provided was reasonable and necessary. *See* 42 C.F.R. § 410.32(d)(3)(i)-(ii).

268. Many of the of the HDL and Singulex requisitions for clinical laboratory testing performed for Dr. Miller's patients between October 2012 and December 2012 lack a diagnosis and an order for particular tests. While HDL would contact Dr. Miller's office if no tests were selected or if the diagnosis was missing from the requisition, Singulex would not contact Dr. Miller to obtain testing and diagnosis information before performing the tests.

269. After Defendant HDL added the Early CDT-Lung test in 2012, Dr. Miller also referred patients to HDL for the lung test, but he did not provide an additional diagnosis related to the lung test. HDL did not, however, contact Dr. Miller's office to obtain a diagnosis to support the medical necessity of the lung test.

270. Nearly blank laboratory requisitions, those that lacked information on tests ordered or a diagnosis to support HDL or Singulex testing, were not valid referrals.

271. Relators believe, and therefore aver, Defendants HDL and Singulex performed laboratory testing and billed government healthcare programs for numerous testing services without a proper referral.

E. **LabCorp Gives Dr. Miller Free Lab Services**

272. For most of Relator Webster's employment, Dr. Miller's staff did not perform either the venipuncture (blood draws) or processing services for blood drawn in Dr. Miller's office when patients were referred for clinical laboratory testing.

273. On the very rare occasion when Dr. Miller's staff would perform blood draws (venipuncture) and processing services for his patients, Dr. Miller's practice would bill Government healthcare programs only for the venipuncture using HCPCS Code 36415. The 2012 Medicare reimbursement for the professional fee for a blood draw is $3.00 per patient, irrespective of the number of samples (vials) drawn. Dr. Miller was not entitled to seek reimbursement for processing services from Medicare.

274. The vast majority of the time, Dr. Miller has used a variety of independent laboratories to perform blood draws and processing services in his office for patients he referred for clinical laboratory testing. From approximately late 2008 until September 2010, Dr. Miller's blood draws and processing services were performed by Executor Diagnostics, LLC. For the last couple of months of 2010 until January 2011, Spectrum Laboratory Network did blood draws and processing for Dr. Miller's patients. In early 2011, Solstas Lab Partners briefly performed lab technician services.

275. Relators believe that LabCorp began providing free lab services (blood draws and processing services) in Dr. Miller's office in spring 2011.

1. **HDL, Singulex, and LabCorp**

276. After BlueWave, Carnaggio, and Dent began marketing Defendant HDL's services, Dr. Miller switched from Berkeley to Defendant HDL (at the end of 2009 or the very beginning of 2010). From 2010 until September 2011, HDL and Singulex supplied Dr. Miller's office with a centrifuge. This centrifuge was used by the lab companies Dr. Miller used during that time period, including Executor, Solstas, and LabCorp.

277. In early 2011, LabCorp installed its own lab technician, Carletha Harris, in Dr. Miller's office. Since then, LabCorp has provided Dr. Miller with free blood draw and blood sample processing services for all referrals for clinical laboratory testing, including referrals to HDL and Singulex, as well as to LabCorp.

278. A recent LabCorp advertisement for a Patient Service Technician Specialist ("PST"), or phlebotomist, in the Charlotte, NC area includes the following requirements for Harris' position: phlebotomy certification; completion of an approved phlebotomy training course; 2 years of experience as a patient service technician/phlebotomist; and proficiency in blood collection by venipuncture and urine collection; and use of LabCorp's technology (including "electronic reporting"). LabCorp's PSTs perform blood collection and processing, as well as packing and shipping of specimens.

279. Harris is paid by LabCorp to perform blood draws and to process blood samples for patients referred by Dr. Miller to Defendants LabCorp, HDL, and Singulex.

280. Harris has worked in this capacity for several years. When Dr. Miller changed office locations on October 3, 2011. LabCorp technician Harris and her equipment moved with Dr. Miller to his new practice location. LabCorp had always provided the following blood draw equipment to Dr. Miller's office (before and after the move): draw chair; LabCorp computer;

copier; refrigerator; and blood draw supplies (needles, butterfly bandages, alcohol pads, etc.). When Dr. Miller moved his practice, LabCorp also supplied Dr. Miller's office with a centrifuge.

281. Here, according to HDL and Singulex arrangements and literature, these Defendants pay Dr. Miller handsomely to perform "processing services" for blood samples drawn on patients referred to HDL and Singulex for testing. These HDL and Singulex processing services are purportedly the responsibility of Dr. Miller's staff. In reality, LabCorp pays Harris to perform nearly 100% of the processing services for all patient blood samples, including those destined for Defendants HDL and Singulex laboratories.

282. Defendants HDL and Singulex are aware of and encourage this arrangement between Dr. Miller and LabCorp as it aids their business model, which requires that blood is drawn in the physician's office in order to create the illusion that the kickback payments are fees to compensate the physician for blood draw and "processing" services.

2. LabCorp Demands A Fee If Dr. Miller Does Not Refer To LabCorp

283. Sometime in 2011 or 2012, Jason Erxleben, Key Account Executive, became the LabCorp marketing representative responsible for sales to physicians in the Florence, SC area, where Dr. Miller's office is located.

284. Since that time, Mr. Erxleben has provided ongoing customer service to LabCorp customer, Dr. Miller.

285. In that capacity, Mr. Erxleben last visited Dr. Miller's office during September 2012.

286. Before September of 2012, Mr. Erxleben provided lunch for Dr. Miller and his staff. At that time, he requested that Dr. Miller refer patients to LabCorp for a Lipid Cascade and not to HDL for a lipid panel.

287. In September of 2012, Dr. Miller told Erxleben that he refused to stop referring patients to HDL for the lipid panel. Erxleben then informed Dr. Miller and/or Dr. Miller's office manager that LabCorp wanted to charge Dr. Miller a $5.00 fee, per patient. Erxleben made it clear that LabCorp was willing to continue to provide Dr. Miller with free blood draw and processing services for referrals to Defendants HDL and Singulex as long as LabCorp also received referrals from Dr. Miller for lipid testing.

288. As stated above, the agreement between Defendants BlueWave and Singulex authorizes BlueWave to pay independent lab companies, such as LabCorp, to draw or process blood samples for Singulex. However, Relators do not believe that Defendant BlueWave pays independent lab companies, such as LabCorp, to draw or process blood samples for patients Dr. Miller refers to Singulex.

289. Relators allege upon information and belief that Defendant BlueWave has an agreement with HDL which, like the agreement with Singulex, authorizes BlueWave to pay independent lab companies, such as LabCorp, to draw or process blood samples for HDL. However, Relators do not believe that Defendant BlueWave pays independent lab companies, such as LabCorp, to draw or process blood samples for patients Dr. Miller refers to HDL.

290. To the contrary, LabCorp appears to pay the draw fee to HDL. LabCorp reports for many of Dr. Miller's patients whose blood was drawn on December 10 and December 11, 2012 contain the following notation in the "additional information" section: "DRAW FEE TO HDL." These patients' blood samples were drawn while the regular LabCorp technician, Harris, was on vacation.

291. Relators believe for the first day and a half (December 10 and half of December 11, 2012), the replacement LabCorp technician noted in the LabCorp computer that the draw fee

for these patients was to go to HDL. These documents support the conclusion that LabCorp and HDL have an arrangement regarding draw fees for patients referred to LabCorp by physicians, such as Dr. Miller, who refer patients to HDL as a result of HDL's inducements.

292. While LabCorp may be entitled to compensation for the blood draws by billing Government healthcare programs, HDL which does not perform the blood draws, is not.

F. Defendants HDL and Singulex Offer Significant Remuneration (In Cash and In Kind) to Physicians for Referrals

293. Defendants HDL and Singulex created and maintained records of the illegal inducements they paid to Dr. Miller. In particular, Defendants HDL and Singulex recorded on a "Draw Log" for each patient referred by Dr. Miller, the name of the patient, the date of birth, the date of the referral, and payment to Dr. Miller for the referral. Singulex has very recently changed the name of the referral log to "Process and Handling" log.

294. Relators have reviewed lists of many of the patients Dr. Miller referred to Defendants HDL and Singulex, as well as documents, including checks, showing substantial cash payments made by HDL and Singulex to Dr. Miller for patient referrals.

1. HDL Kickbacks: $130,000-Plus

295. Relator Lutz has reviewed many referral logs for patients referred by Dr. Miller to HDL between 2010 and 2012. Each HDL referral log contains multiple sheets of tables detailing patients Miller referred for HDL testing.

296. For example, between August 10, 2010 and May 19, 2011, Dr. Miller referred 1,611 patients to HDL. In exchange, Defendant HDL paid remuneration (kickbacks) to doctor Miller, at $20 per patient, for a total of $32,220.00 in just a 9-month period.

297. Since January 2010, based upon Dr. Miller's referral history, Relators estimate, based on 185 referrals per month, that HDL's kickback payments to doctor Miller, at $20 per

patient referred, exceed $133,000. Recently, Dr. Miller has referred more than 200 patients per month to HDL.

2. **Singulex Kickbacks: $55,000-Plus**

298. Relator Lutz also reviewed the referral logs for patients referred by Dr. Miller to Singulex.

299. During the same nine-month period (between August 10, 2010 and May 19, 2011), and based on Dr. Miller's practices, Dr. Miller referred 1,611 patients to Defendant Singulex. In exchange, the remuneration Singulex paid Dr. Miller, at $10 per patient, was $16,110.00.

300. Relators estimate that, based on 185 patient referrals per month, since July 2010, Singulex paid remuneration (kickbacks) to Dr. Miller, at $10 per patient referred, in excess of $55,000. Recently, Dr. Miller has referred more than 200 patients per month to Singulex.

G. Defendants' HDL, Singulex and BlueWave National Scheme: Inducing Referrals for Lab Tests

1. BlueWave's Founders Deliver the HDL and Singulex Promotions: Fees for Patient Referrals

a. The National Scope of HDL's Scheme

301. Upon information and belief, before their January 1, 2010 departure from Berkeley, the founders of Defendant BlueWave (Dent and Johnson) and Defendant HDL collaborated to develop a nationwide marketing program for HDL.

302. Relators allege upon information and belief, that HDL's offer of $20.00 processing fees to referring physicians was approved by HDL as part of the marketing program delivered by BlueWave to all potential HDL customers nationwide.

303. HDL's product manual is called the "In Service Guide for Lab Partners" in recognition of the physicians who "partner" with HDL through compensation arrangements.

304. Upon information and belief, Defendant BlueWave's sales representatives offered the same cash inducements to many physicians (in addition to Dr. Miller) to induce them to refer patients to Defendant HDL for laboratory testing. For example, Relators allege upon information and belief that many physicians in North Carolina (including the Western District of North Carolina), South Carolina, and Georgia received the same promotional offer, namely HDL's offer of inducements that Defendant BlueWave made to Dr. Miller.

305. In the fall of 2012, Blue Wave's Dent and Carnaggio provided Dr. Miller with HDL's marketing materials for the EarlyCDT-Lung test, including a page of suggested ICD-9 codes. These same marketing HDL marketing materials and suggested ICD-9 codes for HDL's lung test are distributed by HDL representatives from Florida to Pennsylvania.

306. As stated above, Kyle J. Martel, one of the original BlueWave sales representatives, began promoting HDL and Singulex products in Florida in 2010.

307. In 2012, Martel and Charles A. Maimone, Jr. formed "C&K Healthcare Consultants." Maimone, who is based in New Jersey, is listed as the HDL representative on a sample HDL new customer form that was recently provided to a physician practice in Pennsylvania. HDL's new customer form was last revised in 2010.

308. Relators believe, and therefore aver, that Maimone promotes HDL and Singulex products in New Jersey and/or Pennsylvania, and that he uses the same marketing materials and offers the same inducements that BlueWave, HDL, and Singulex have been promoting since 2010.

309. Relators allege upon information and belief, that Defendant HDL's national marketing practices, as promoted by BlueWave, resulted in many physicians (in addition to Dr.

Miller) receiving a $20.00 per patient "processing services" fee each time a patient is referred to HDL.

310. Relators allege upon information and belief that, utilizing this model, Defendants BlueWave and HDL implemented a marketing program which resulted in illegal inducements being paid to referring physicians in all of the 45 states where Defendant HDL operates.

311. The national scope of HDL's inducement scheme is also supportive by HDL's CEO, who has stated that HDL's business practices include obtaining W-9 forms from physicians as they become new customers. This W-9 form is necessary for HDL to issue 1099 forms reflecting the compensation arrangement that HDL has with many physicians throughout the United States. HDL pays physicians nationwide for "processing services."

b. HDL Induced Physicians to Switch Overnight

312. As former sales representatives for HDL's competitor, Berkeley, BlueWave's original sales representatives would have access to information regarding physicians with robust practices and valuable referrals. For example, at the end of 2009, Dr. Miller was the number one prescriber of Berkeley tests in Defendant Dent's sales territory, which included North Carolina, South Carolina and Georgia.

313. Just one week into 2010, after Defendant BlueWave (through its founder Defendant Dent, and Carnaggio) began promoting HDL testing, Dr. Miller stopped referring patients to Berkeley and started referring patients to HDL. Thereafter, HDL started paying Dr. Miller a $20.00 per patient referral.

314. Relators allege upon information and belief Dr. Miller is only one of many former Berkeley customers who switched their referrals to HDL after BlueWave started promoting HDL clinical laboratory testing services. Relators further allege upon information and belief that, after

they changed referrals to HDL, many other physicians received HDL's $20.00 per patient fee for "processing services."

315. Defendant HDL's practice of offering and paying a $20.00 per patient inducement to Dr. Miller continues today. HDL's practice of offering and paying a $20.00 per patient inducement to other referring physicians is also ongoing.

c. BlueWave Delivers Singulex Offers of "Processing Fees"

316. In June 2010, Defendant BlueWave (through its founder Defendants Dent and Johnson, and sales representative Carnaggio) began promoting Singulex testing. By July 2010, Dr. Miller was referring nearly every patient to Singulex. Thereafter, Singulex started paying Dr. Miller a $10.00 per patient fee. Singulex refers to these as fees for "processing services."

317. Relators also allege upon information and belief, that BlueWave facilitated an offer by Singulex to pay Dr. Miller a $10.00 fee for each patient referred.

318. Relators allege upon information and belief that Defendant BlueWave's founders carried out promotional programs with Dr. Miller that were vetted and approved by Singulex for delivery to all potential Singulex customers in all states covered by Singulex and BlueWave promotional agreements.

319. Relators allege upon information and belief that, since June of 2010, Defendants Singulex and BlueWave have used the same marketing practices throughout BlueWave's sales territories that they employed with Dr. Miller in order to induce many physician customers to refer their patients to Defendant Singulex.

320. Defendant Singulex's practice of offering and paying a $10.00 per patient inducement to referring physicians throughout the country, including Dr. Miller, continues to today.

2. BlueWave and HDL Grab Physician Referrals in Many States

321. The sales territory served by Defendant BlueWave's sales representatives Carnaggio and Dent while they worked at Berkeley, HDL's competitor, was North Carolina, South Carolina, and Georgia.

322. Since January 2010, Defendant BlueWave, its principals, and agents have marketed HDL testing services in many states, including: North Carolina, South Carolina, Georgia, Florida, California, Colorado, Louisiana, Missouri, Mississippi, New Jersey, New York, Texas, Tennessee, Virginia and Wisconsin.

323. In addition to Dr. Miller, many former Berkeley physician customers from across the United States stopped referring patients to Berkeley after BlueWave started promoting HDL testing. These physicians include: Dr. Thomas L. Jeffries of Raleigh, NC; Dr. Gerald M. Kovar of Tarzana, CA; Dr. Michael Rosemore of Hueytown, AL; and Dr. James Mensone of Greenville, SC.

324. Defendants BlueWave, Dent, Johnson, and HDL have promoted HDL products to former Berkeley physician customers in the following states: Alabama, California; Colorado; Florida; Kansas; Louisiana; Missouri; Mississippi; New Jersey; South Carolina; Texas; and Virginia.

325. HDL's national promotional program has included offering potential physician customers "processing fees" for each patient referred to HDL.

326. Upon information and belief Defendant BlueWave's sales representatives offered the same cash inducements they offered to Dr. Miller to many physicians across the United States, including former customers of Berkeley as well as new targets, to induce them to refer patients to Defendant HDL for laboratory testing.

327. Relators allege upon information and belief that since at least January of 2010, like Dr. Miller, many physicians throughout the United States refer patients to HDL and have accepted HDL's offer of bogus "processing fees" in exchange for each patient referral to HDL.

328. Upon information and belief, since at least January 2010, HDL has made monthly processing services payments to many, if not all, of its referring physicians. HDL pays the referring physician $20.00 each time a patient is referred for HDL testing.

329. HDL reports that it serves 10,000 physicians. Dr. Miller, one of the first customers to switch from Berkeley to HDL, is identified on HDL's inducement checks as HDL Customer No. 041. Relators allege upon information and belief that many HDL physician customers receive similar inducement checks ($20.00 per patient referral), signed by Defendant Mallory, from Defendant HDL.

a. **BlueWave Markets Singulex Inducements in Many States**

330. Upon information and belief, around June 2010, Defendant BlueWave and Defendant Singulex developed a program for marketing Singulex's testing services in all states covered by Singulex and BlueWave marketing agreements.

331. Since June 2010, Defendant BlueWave has had the exclusive right to market Singulex laboratory testing services in ever-expanding geographic areas. For example, since June 2010, Defendant BlueWave has had the exclusive contract to market Singulex testing in North Carolina, South Carolina, Georgia, and in other areas across the United States.

332. Dr. Miller is one of many physicians in BlueWave's Singulex territory. Based on the marketing of BlueWave's representatives, Dr. Miller began to refer patients to Singulex in mid-2010.

333. Thereafter, Singulex began making significant monthly cash payments to Dr. Miller. Singulex called these payments "draw fees," which were calculated at $10.00 each time Dr. Miller referred a patient to Singulex.

334. As stated above, Martel, one of the original BlueWave sales representatives, promotes HDL and Singulex products in Florida. Martel's partner in C&K Healthcare Consultants, Maimone, is based in New Jersey. HDL and Singulex promotional materials identifying Maimone as the sales representative were recently provided to a physician practice in Pennsylvania. These materials included the Singulex new customer form. Singulex has provided a space on the new customer form for the sales representative to request a 1099 for the new physician.

335. Upon information and belief, the inclusion of the 1099 form request on the Singulex new customer form supports the conclusion that Singulex pays process and handling fees to referring physicians with great frequency, and that Singulex marketing agents offer these process and handling arrangements to prospective new customers in exchange for patient referrals.

336. Relators allege upon information and belief that many physicians in North Carolina , South Carolina, Georgia, and other states received the same promotional offer from Defendant BlueWave that was made to Dr. Miller.

337. Relators allege upon information and belief that the marketing program vetted and approved by Singulex and its former CEO, Defendant Goix, for potential customers in all states covered by Singulex and BlueWave marketing agreements included Singulex's offer of a $10.00 inducement for each patient referral.

338. Upon information and belief, Defendant BlueWave's sales representatives conveyed to physicians across the country Singulex's offer to pay the physician cash remuneration of $10.00 each time the physician referred a patient to Defendant Singulex for laboratory testing.

339. For example, Defendant Brad Johnson, President of Defendant BlueWave, and an equity owner of Defendant Singulex, marketed Singulex products to many physicians in Alabama. Relators allege upon information and belief that Defendants Johnson and Dent (as co-founders and executives of BlueWave) would deliver only marketing programs vetted with and approved by their client, Defendant Singulex.

340. Relators allege upon information and belief that since at least June of 2010, many referring physicians throughout the United States (in addition to Dr. Miller) have accepted Singulex's offer of illegal remuneration.

341. Relators allege upon information and belief that Defendant Singulex has received referrals from physicians (in addition to Dr. Miller) receiving bogus "processing fees" from Singulex. Relators further allege upon information and belief that Defendant Singulex has submitted claims for these tainted and unnecessary laboratory testing services to Government healthcare programs.

342. Upon information and belief, physicians in many states who refer patients to HDL and Singulex receive substantial remuneration from HDL and Singulex based on national marketing schemes vetted and approved by Defendants HDL and Singulex and carried out by Defendant BlueWave. These marketing schemes have resulted in HDL and Singulex submitting many claims for tainted and unnecessary laboratory testing services to Government healthcare programs.

343. Defendant Johnson, BlueWave's co-founder, has described his target physician customer as "early adopters, cutting edge physicians, draw their own blood, have the ability to draw their own blood, money hungry," smaller practices.

344. Since 2010, HDL and Singulex have focused on physicians with the capacity to draw their own blood. In fact, the new customer sheets for both HDL and Singulex focus on whether the physician draws blood for patients in his or her office.

345. Relators allege upon information and belief that BlueWave targets physicians who have the ability to have patient blood drawn in their offices (as opposed to a hospital lab or other outside laboratory) because if the patient is sent to a lab outside the doctor's office, all of the "processing" would be done there. HDL and Singulex would then have no justification for the bogus "processing fees" they pay to physicians to induce referrals.

3. False Records to Get False or Fraudulent Claims Paid: Singulex and HDL "Processing" Agreements with Referring Physicians

346. Defendant Singulex has recently entered in a written agreement with Dr. Miller titled "Agreement for Singulex Clinical Lab Cardiovascular Testing." Relators believe that this is the first time that Defendant Singulex has put in writing its $10.00 per patient compensation arrangement with Dr. Miller.

347. Based on statements by Defendant HDL's CEO, Defendant Mallory, that HDL has compensation arrangements to pay referring physicians "processing fees," Relators believe, and therefore aver, that Defendant HDL has also created written agreements with referring physicians, including Dr. Miller.

348. Upon information and belief, Defendants HDL and Singulex enter into written agreements like the Singulex "Agreement for Singulex Clinical Lab Cardiovascular Testing" with referring physicians nationwide.

349. Compensation arrangements between HDL or Singulex and referring physicians purport to characterize remuneration paid by Defendants HDL and Singulex as "professional service fees" for "processing and handling" blood samples for patients referred to Defendants HDL and Singulex.

350. In reality, Relators know that many referring physicians, such as Dr. Miller, do not perform the services for which they are ostensibly responsible according to the processing agreements with HDL and/or Singulex. Even if the physicians performed the "processing" services listed, the fair market value of the services is far less than the amounts paid by Defendant Singulex ($10.00) and by Defendant HDL ($20.00) for each patient referred.

351. Defendants HDL, Mallory, Singulex, and Goix then submit or cause the submission of claims to the Government for these referred patients' laboratory tests, even if the services are unnecessary, duplicative, or worthless (*e.g.*, the patient has not fasted sufficiently prior to testing), and receive routinely payment worth hundreds of dollars in return.

352. Upon information and belief, at no point in time have Defendants HDL, Mallory, Singulex, and Goix returned such payments to the Government as an overpayment.

353. The agreements for "processing and handling" of blood samples created by or on behalf of Defendants HDL and Singulex are false records because they purport to disguise fraudulent inducements as fair market compensation for bona fide physician services.

4. BlueWave Conspires with HDL and Singulex to Offer Kickbacks

354. The marketing efforts of BlueWave involve interaction with prospective referring physicians, including visiting physician offices, interacting with office staff, and providing promotional materials. Upon information and belief, Defendant BlueWave, Carnaggio, Defendant Dent, and other BlueWave sales representatives communicated HDL and Singulex marketing messages to potential referring physicians throughout the country.

355. Relators know that as a result of Defendant BlueWave's marketing efforts, Dr. Miller referred many patients to HDL and Singulex. Thereafter, Dr. Miller received cash inducements for his referrals.

356. Relators allege upon information and belief that since at least January 2010, Defendant BlueWave has facilitated the offer and acceptance of inducements by Defendants HDL and Singulex, by delivering the laboratories' marketing messages, and providing ongoing customer service.

357. Relators allege upon information and belief that since at least January 2010, Defendant HDL has offered bogus "processing fees" of $20.00 per patient to induce referrals, including through Defendant BlueWave, to physicians throughout at least the following states: Alabama, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, South Carolina, Texas, Virginia, Washington and Wisconsin.

358. Relators allege upon information and belief that since at least June 2010, Defendant Singulex has offered bogus "processing fees" of $10.00 per patient to induce referrals, including through Defendant BlueWave, to physicians throughout the following states: Alabama, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee and Texas.

359. Relators believe, and therefore aver, that as a result of Defendant BlueWave's efforts to deliver Defendants' HDL and Singulex's offers of inducements, many physicians in the afore-mentioned states have accepted the offer of bogus "processing fees" from HDL and

Singulex, and have referred patients to HDL and/or Singulex. Relators believe that many of these patients are beneficiaries of Government healthcare programs or private insurance plans.

5. Role of Independent Lab

360. Defendant BlueWave's founder, Brad Johnson, has highlighted the importance of in-office blood drawing services when BlueWave targets potential customers for Defendants HDL and Singulex.

361. Physicians can have the capacity to provide their patients with in-office blood drawing services either by employing a lab technician as a member of the doctor's staff - or by obtaining lab technician services paid for by an independent laboratory.

362. The new customer forms for both HDL and Singulex contain information regarding whether blood draws are performed in the doctor's office. BlueWave's, HDL's and Singulex's focus on physicians able to draw blood in their office adds to the fraudulent nature of their scheme. Government healthcare programs and private insurers reimburse laboratory testing that is medically necessary. Physicians can order only tests that are necessary for the treatment of Government healthcare program beneficiaries. It should not matter to the physician, or to the laboratory testing provider, whether the blood is drawn in the physician's office or at an outside lab.

363. The location of the blood draw is, however, critical to HDL and Singulex because these tests are marketed as a revenue stream for the referring physician. For the stream of inducements to flow from HDL and Singulex, the blood draws and processing services for HDL and Singulex tests must be provided in the office of the doctor receiving the inducements so that the Defendants can disguise the inducements as "processing" fees.

364. If the patient leaves the doctor's office and has blood drawn at an outside lab, that lab would also perform the blood processing services. HDL and Singulex could not then pay the

referring physician the bogus "processing" fee. Physicians must either employ a lab technician or obtain the services of a technician from an independent lab to benefit from the HDL and Singulex inducements.

365. All of the claims for HDL and Singulex testing performed for Government program beneficiaries as a result of referrals from physicians receiving inducements from HDL and/or Singulex are tainted by federal AKS violations. These claims also violate the analogous state anti-kickback laws.

366. In violation of federal and state anti-kickback laws, Defendants HDL and Singulex tested beneficiaries and submitted claims to the Government healthcare programs based on illegally induced referrals. *See* Exhibit "A."

367. Compliance with the federal AKS, and analogous state laws is a condition of payment by federal and state healthcare programs. All of the claims submitted by HD and Singulex based on fraudulently obtained physician referrals also violate federal and state false claims acts.

368. Relators allege upon information and belief that Defendants' business scheme results in systematic nationwide submissions of false claims to Government healthcare programs and private insurance plans for hundreds of millions of dollars in false claims for clinical laboratory tests tainted by anti-kickback violations and Stark violations, and other testing which was not medically necessary.

VIII. Defendants' Illegal Inducements Expose Patients to Harm

369. Defendants' scheme also exposes beneficiaries of Government healthcare programs to significant physical and economic harm.

A. **Physical Harm Caused by Defendants' Tainted Laboratory Tests**

370. Defendants' scheme causes real suffering for patients who are the pawns at the center of the Defendants' fraudulent conduct. Exploited patients, most of whom are elderly Medicare beneficiaries, are subjected to painful and unnecessary needle sticks. Where the patient is referred for the full panel of HDL and Singulex testing, the lab requires eight to nine vials of the beneficiary's blood to perform these tests. These excessive and unnecessary blood draws are especially intolerable for elderly patients.

371. Relator Webster has witnessed patients complaining of lightheadedness, loss of blood, and painful needle sticks resulting from the Defendants' fraudulent testing scheme.

372. The foreseeable effect of the Defendants' scheme, which follows from referrals initiated in response to the Defendants' inducements, includes prescription medications. Physicians, including Dr. Miller, unnecessarily prescribe medications to justify Defendants' HDL's and Singulex's laboratory testing.

373. At the time of the initial false diagnosis of high cholesterol, nearly every one of Dr. Miller's patients is prescribed cholesterol-lowering medications in order to both support the diagnosis of high cholesterol and also to justify the referrals to HDL and Singulex.

374. For example, Dr. Miller prescribed medications for the treatment of high cholesterol to almost all patients referred to HDL and Singulex. These include Crestor (Rosuvastatin), which is manufactured by AstraZeneca. Crestor can have serious side effects, including a muscle problem known as rhabdomyolysis, which can lead to kidney problems, and liver damage. Patients may suffer severe muscle pain as a result of consuming the drug.

375. In addition, Dr. Miller also prescribes Simcor for nearly every patient referred to HDL and Singulex. Simcor, which is manufactured by Abbott Labs, also has serious side effects,

including rhabdomyolysis. Statins like Simcor and Crestor put patients at risk for developing serious health conditions, including, but not limited to, diabetes and memory loss.

376. Relator Webster has observed patients complaining of the ill effects of these medications. In response, Dr. Miller advises the patients to continue taking medication.

377. Relators believe that physicians who are offered Defendant HDL's and Defendant Singulex's inducements, initiate and maintain prescription drug therapy in part to justify referrals to Defendants HDL and Singulex that will result in ongoing cash remuneration for referring physicians.

B. **Defendants' Tainted Laboratory Tests Cause Economic Harm to Patients**

378. To further its fraudulent scheme, some physicians, including Dr. Miller, make misrepresentations to patients that they suffer from conditions which require the Defendants' (HDL's and Singulex's) testing and/or medications to treat these conditions.

379. Patients also suffer from the negative economic impact of inaccurate diagnoses of high cholesterol used to justify Defendants' (HDL's and Singulex's) testing. Other economic harm to patients includes: unnecessary follow-up appointments with physicians to review unnecessary lab results; co-payments for unnecessary prescription drugs; costs for care related to side effects from unnecessary prescriptions; and increased insurance premiums related to increased testing, prescription usage, and related false diagnoses.

380. For example, Relators are aware of patients who have been denied life insurance coverage because the patient has been falsely diagnosed with high cholesterol. There are times when the patients referred to HDL and Singulex are not even aware that they have been given this diagnosis. Patients have contacted Dr. Miller's office to complain about the fabricated high cholesterol diagnosis. When this occurred, the office manager has changed the patient record to

remove the fabricated diagnosis of high cholesterol and has written a letter to the insurance company stating that the patient was diagnosed with high cholesterol in error.

381. In addition to prescriptions for cholesterol-lowering medications, Dr. Miller also prescribes Metanx #180, 1 tablet BID (twice a day), manufactured by PamLab, LLC. Dr. Miller tells patients that Metanx improves good cholesterol. However, the FDA-approved label states that Metanx is approved only for the narrow indication of diabetic neuropathy. PamLab provided Dr. Miller with pre-printed scrip pads and samples. Dr. Miller prescribes PamLab products electronically.

382. Metanx costs approximately $82.56 per month. The average cost for a patient in a state-funded program, *i.e.*, a participant in the South Carolina Employee Insurance Program, is $41.10 for a 30-day supply.

IX. Defendants' Scheme Causes Government Healthcare Programs to Pay Millions of Dollars for Unnecessary, Useless, and Even Harmful Clinical Laboratory Testing

A. Defendants Scheme to Submit or Cause the Submission of False Claims

383. Defendants' scheme of inducing physicians to refer patients to Defendants HDL and Singulex for unnecessary clinical laboratory testing included, but was not limited to, the following conduct which is ongoing:

- Defendant BlueWave marketed the testing services of Defendants HDL and Singulex to referring physicians;
- In violation of state and federal false claims statutes, and federal and state anti-kickback laws, Defendant HDL offered physicians $20 for each patient referral to HDL;

- In violation of state and federal false claims statutes, and federal and state anti-kickback laws, Defendant Singulex offered physicians $10 for each patient referral to Singulex;
- Defendant BlueWave conspired with Defendants HDL and Singulex or otherwise facilitated the offers of cash remuneration to referring physicians in violation of state and federal false claims statutes, and federal and state anti-kickback laws;
- In violation of state and federal false claims statutes, federal and state anti-kickback laws, physicians received and accepted offers of remuneration to refer patients to HDL and Singulex for testing, even where testing was not medically necessary.

384. In furtherance of the Defendants' scheme, the Defendants' conduct included making or causing to be made or used false records or statements material to false or fraudulent claims, including, but not limited to:

- false records to create the appearance that cash remuneration paid by HDL and Singulex to physicians in exchange for patient referrals were for legal and appropriate professional services to be performed by referring physicians;
- false records to otherwise create the appearance that Defendants' (HDL's and Singulex's) testing did not violate the AKS and/or was otherwise reimbursable by government healthcare programs or private healthcare insurance companies;
- false requisitions for HDL and Singulex testing that were material to false or fraudulent claims submitted to Medicare, Medicaid, and other Government healthcare programs and private insurers; and

- other false records or statements, including false patient records, material to false claims submitted to Medicare, Medicaid, and other Government healthcare programs and private payors.

385. Relators believe that Defendants HDL and Singulex utilized this scheme in every state across the country where HDL or Singulex pays physicians inducements to obtain fraudulent referrals of patients, including Government program beneficiaries, for laboratory testing services.

386. Relators believe that Defendants employed and/or have conspired to employ this scheme to submit false claims to federal and state healthcare programs including Medicare, Medicaid, CHAMPUS/TRICARE, and other federal and state healthcare programs.

387. Each and every claim that was billed to a Government healthcare program, including Medicare and/or Medicaid, for a test performed on a patient referred to HDL and Singulex by a physician who received cash inducements from Defendant HDL or Defendant Singulex violates the federal and state false claims acts.

388. Many of these testing services referred to Defendants HDL or Singulex also violate federal and state false claims acts because the tests were not medically necessary, and therefore, not covered by Government healthcare programs.

389. Relators believe that Defendants employ and/or conspire to employ this scheme to submit false claims to private insurers in California and Illinois. Defendants submitted claims for testing to commercial insurance companies including AETNA and Blue Cross. Examples of Blue Cross patients who were referred to the Defendants for testing are provided in Exhibits "B" and "C."

390. Each and every claim that was billed to a private insurer in California or Illinois, or for a patient located in those states, for a test performed on a patient referred to HDL or Singulex by a physician who received cash inducements from Defendant HDL or Defendant Singulex violates the CIFPA and ILCFPA.

391. Upon information and belief, many of these testing services referred to Defendants HDL or Singulex also violate the conditions of payment by private insurance companies in California or Illinois because the tests they performed and billed for were not medically necessary, and therefore, not covered.

B. Damages to Government Healthcare Programs: Millions in Reimbursements

392. Defendants HDL and Singulex derive a significant portion of their earnings from reimbursements for claims submitted to Government healthcare programs.

393. Relators believe that the Defendants' fraudulent conduct and illegal inducements to referring physicians led to exponential growth in revenues for Defendants HDL and Singulex over the past two years. For example, the marketing scheme employed by BlueWave and HDL successfully catapulted Defendant HDL to the forefront of cholesterol testing market.

394. The payoff for these laboratories has been rapid and dramatic.

395. For example, a single referring physician, such as Dr. Miller, has referred and continues to refer thousands of patients to Defendants HDL and Singulex each year. Recently, Dr. Miller has referred more than 200 patients per month to Defendants HDL and Singulex.

396. Relators allege upon information and belief that a large percentage of patients referred for laboratory testing by physicians receiving inducements from Defendants HDL and Singulex are beneficiaries of Government healthcare programs, including Medicare and TriCare. For example, between August 10, 2010 and September 8, 2010, of the 200 patients referred to HDL by Dr. Miller, 98 were Medicare beneficiaries (age 65 and over). Additional patients

referred by Dr. Miller were beneficiaries of TRICARE/CHAMPUS, and other federal or state employees' health benefit programs.

1. **HDL Claims Average $1,400 Per Beneficiary, 3-4 Times a Year**

397. Relators allege upon information and belief that for each Government healthcare program beneficiary referred for testing by a physician receiving HDL's cash inducements, HDL submits a claim to federal and state healthcare programs for more than $1,400.00 per episode, and that Defendant HDL submitted claims for these expensive tests three to four times per year for every affected Medicare or Government beneficiary.

398. Significantly, through Dr. Miller alone, Defendant HDL received 886 tainted referrals for laboratory testing between August 11, 2010 and December 30, 2010. Of the 886 claims HDL submitted for these patients, approximately 416 were for Medicare-eligible patients (aged 65 and older). More patients referred to HDL were beneficiaries of other federal and state healthcare programs, such as CHAMPUS/TRICARE and the state employees' health benefit program.

399. A table summarizing some of the patients for whom claims submitted by Defendant HDL to Medicare and other Government payors is attached as Exhibit "B."

2. **Singulex Reimbursements Average $300 Per Beneficiary Per Episode**

400. Relators allege upon information and belief that for each Government healthcare program beneficiary referred for testing by a physician receiving Singulex's cash inducements, Singulex submits a claim to federal and state healthcare programs for more than $300 per testing episode, and that Singulex submitted claims for these expensive tests three to four times per year for every affected Medicare or Government beneficiary.

401. Significantly, through Dr. Miller alone, Relators believe, and therefore aver, that Defendant Singulex submitted 886 tainted claims for laboratory testing between August 11, 2010

and December 30, 2010. Of the 886 claims submitted, approximately 416 were for Medicare-eligible patients (aged 65 and older). Additional patients referred to Singulex by Dr. Miller were beneficiaries of other federal and state healthcare programs, such as CHAMPUS/TRICARE and the state employees' health benefit program.

402. A table summarizing some of the patients for whom Defendant Singulex submitted claims to Medicare and other Government payors is attached as Exhibit "C."

COUNT I

(UNITED STATES EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS)
Violation of the Federal False Claims Act
31 U.S.C. § 3729(A)(1)(A), (B) AND (C)

403. Relators re-allege Paragraphs 1 through 402 as though fully set forth herein.

404. Defendants violated the federal False Claims Act by submitting claims, or causing the submission of claims, for reimbursement from federal health care programs, including Medicare and Medicaid, knowing that they were ineligible for the payments demanded.

405. Claims submitted, or that were caused to be submitted, by the Defendants for clinical laboratory testing that violated the federal AKS constitute violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

406. Claims submitted, or that were caused to be submitted, by the Defendants for clinical laboratory testing services that were unnecessary constitute violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

407. Claims submitted, or that were caused to be submitted, by the Defendants for clinical laboratory testing services that were not appropriately provided or were useless constitute violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

408. Defendants knowingly caused to be made or used false records or statements, material to false claims, including, but not limited to: false requisitions for laboratory testing by HDL and Singulex; false certifications of medical necessity; false records of medical necessity; false processing services agreements between HDL or Singulex and referring physicians; false records related to inducements paid to referring physicians; all of which constitute violations of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

409. Defendants, through their concerted efforts to carry out Defendants HDL and Singulex's fraudulent schemes to bill Government healthcare programs for false claims for clinical laboratory testing, conspired to defraud the federal government by getting false or fraudulent claims (including those related to unnecessary services, as well as those claims related to referrals tainted by violations of the federal Anti-Kickback Statute) allowed or paid by the government in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

WHEREFORE, Relators request the following relief:

A. Defendants be ordered to cease and desist from submitting and/or causing the submission of any more false claims or in any way from otherwise violating the federal False Claims Act, 31 U.S.C. §3729 *et seq*.

B. That judgment be entered in favor of the Relators and the United States and against Defendants in the amount of each and every false or fraudulent claim and so multiplied as provided by federal False Claims Act, 31 U.S.C. § 3729(a), plus a civil penalty of not less than Five Thousand Five Hundred ($5,500.00) Dollars nor more than Eleven Thousand ($11,000.00) Dollars per claim, as provided by 31 U.S.C. §3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the

various schemes undertaken by Defendants together with penalties for specific claims to be identified at trial after full discovery;

C. Twenty five percent 25% of the proceeds of this action to the Relators if the United States elects to intervene, and 30% if it does not;

D. That judgment be granted for the Relators and the United States and against Defendants for any costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit;

E. That Defendants be enjoined from submitting, or causing to be submitted, further false claims to government healthcare programs and from attempting to collect monies for claims the Defendants have already submitted, or caused to be submitted; and

F. That Relators and the United States be entitled to any and other relief that they are entitled to, whether by law or equity.

COUNT II

(UNITED STATES EX REL. LUTZ AND WEBSTER V. HDL AND SINGULEX)
Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(1)(G)

410. Relators re-allege Paragraphs 1 through 409 as though fully set forth herein.

411. Defendants HDL and Singulex have received overpayments by Government healthcare programs for illegally-induced and/or medically unnecessary clinical laboratory testing that must be returned.

412. Defendants HDL and Singulex failed to report their submission of false claims for clinical laboratory testing to federal and state government healthcare programs or CMS, and Defendants, HDL and Singulex, also failed to return payments received from government healthcare programs based upon false claims or records.

413. Defendants HDL and Singulex were not entitled to receive payments from government healthcare programs based on claims that were false because: they violated federal the federal Anti-Kickback Statute; they contained false certifications of medical necessity; and/or they contained false certification and/or representations of compliance with federal statutes and regulations, including the federal AKS.

414. Defendants HDL and Singulex used false records to conceal amounts Defendants HDL and Singulex owed government healthcare programs for payments based on unallowable claims and related charges for tainted and unnecessary clinical laboratory testing.

415. As a result of Defendants' HDL and Singulex failure to refund amounts owed to government healthcare programs, Defendants HDL and Singulex submitted false claims in order to avoid or decrease obligations to return overpayments of state and federal funds.

416. The Patient Protection and Affordable Care Act (PPACA), 42 U.S.C. § 1128J(d), which Defendants HDL and Singulex have violated, requires that Defendants HDL and Singulex self-report and return Government healthcare program overpayments within 60 days of identification.

417. Defendants HDL and Singulex knowingly caused to be made or used false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States, in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

WHEREFORE, Relators request the following relief:

A. Judgment against Defendants HDL and Singulex for three times the amount of damages the United States has sustained because of their actions, plus a civil penalty of Eleven Thousand ($11,000.00) Dollars for each violation of the federal False Claims Act;

B. 25% of the proceeds of this action if the United States elects to intervene, and 30% if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, the costs of the audit, and other related expenses;

D. Such other relief as the Court deems just and appropriate.

COUNT III

(NORTH CAROLINA EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS)
NORTH CAROLINA FALSE CLAIMS ACT
N.C. Gen. Stat. § 1-605 *et seq.*

418. Relators re-allege Paragraphs 1 through 417 as though fully set forth herein.

419. This is a claim for damages and penalties under the North Carolina False Claims Act.

420. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

421. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the North Carolina State Government to approve or pay such false and fraudulent claims.

422. By virtue of the acts described above, Defendants conspired to violate the North Carolina False Claims Act.

423. By virtue of the acts described above, Defendants have violated the North Carolina Anti-Kickback Statute, N.C. Gen. Stat. § 108A-63(g)-(j).

424. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements.

425. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligations to return overpayments of state and federal funds to North Carolina Medicaid.

426. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

427. The State of North Carolina is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the North Carolina Medicaid program or other state health care programs have sustained because of Defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of North Carolina Gen. Stat. § 1-607(1), (2), (3) and (7).

B. Twenty five percent (25%) of the proceeds of this action to the Relators if the State of North Carolina elects to intervene, and thirty percent (30%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, the costs of the audit, and other related expenses;

D. Such other relief as the Court deems just and appropriate.

COUNT IV

(CALIFORNIA EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS)
CALIFORNIA FALSE CLAIMS ACT
Cal. Govt Code §§ 12650 *et seq.*

428. Relators re-allege Paragraphs 1 through 427 as though fully set forth herein.

429. This is a claim for treble damages and penalties under the California False Claims Act.

430. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

431. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve or pay such false and fraudulent claims.

432. By virtue of the acts described above, the Defendants conspired to violate the California False Claims Act.

433. By virtue of the acts described above, Defendants have violated and continue to violate California laws prohibiting the payment or receipt of bribes or kickbacks, namely Cal Bus. & Prof. Code § 650, Cal. Welfare & Inst. Code § 14107.2, and Cal. Health & Safety Code § 445.

434. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by the Defendants, paid and continues to pay the claims that are non-payable as a result of Defendants' illegal conduct.

435. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligations to return overpayments of California state funds.

436. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

437. The State of California is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $11,000.00 for each violation of Cal. Gov't Code § 12651(a)(1), (2), (3) and (7).

B. Thirty three percent (33%) of the proceeds of this action to the Relators if the State of California elects to intervene, and fifty percent (50%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

COUNT V

(CALIFORNIA, EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS)
CALIFORNIA INSURANCE FRAUDS PREVENTION ACT
Cal. Ins. Code § 1871.7

438. Relators re-allege Paragraphs 1 through 437 as though fully set forth herein.

439. This is a claim for treble damages and penalties under the California Insurance Fraud Prevention Act.

440. By virtue of the acts described above, Defendants knowingly utilized a scheme by which they improperly procured "runners, cappers, steerers, and other persons" to procure patients who held private insurance contracts and against whom Defendants could file claims for payment. *See* Cal. Ins. Code § 1871.7(a).

441. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the private insurers in California, or for patients in California those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

442. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in California, or for patients in California covered by those insurers, to approve or pay such false and fraudulent claims.

443. By virtue of the acts described above, the Defendants conspired to violate the California Insurance Fraud Prevention Act and each patient's private health insurance contract.

444. The private insurers in California, or those insurers that covered patients in California, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendants, paid and continue to pay the claims that are non-payable as a result of Defendants' illegal conduct.

445. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their respective obligations to return overpayments to these private insurance companies.

446. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

447. Each claim for reimbursement that was a result of the Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

448. The State of California is entitled to the maximum penalty of $10,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages that the private insurance companies have sustained because of Defendants' actions, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 for each violation of Cal. Ins. Code § 1871.7(a) and (b);

B. At least thirty percent (30%) and up to forty percent (40%) of the proceeds of this action to the Relators if the State of California elects to intervene, and forty percent (40%) to fifty percent (50%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

COUNT VI

(ILLINOIS EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS)
ILLINOIS FALSE CLAIMS ACT
740 Ill. Comp. Stat. Ann. §§ 175/1 *et seq.*

449. Relators re-allege Paragraphs 1 through 448 as though fully set forth herein.

450. This is a claim for treble damages and penalties under the Illinois False Claims Act.

451. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

452. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Illinois State Government to approve or pay such false and fraudulent claims.

453. By virtue of the acts described herein, Defendants conspired to violate the Illinois False Claims Act.

454. By virtue of the acts described above, Defendants have violated and continue to violate 305 Ill. Comp. Stat. Ann. 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks).

455. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendants, paid and continues to pay the claims that are non-payable as a result of Defendants' illegal conduct.

456. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or to decrease its obligations to return overpayments of Illinois state funds.

457. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

458. The State of Illinois is entitled to the maximum penalty of $11,000.00 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 740 Ill. Comp. Stat. Ann. § 175/3(a)(1), (2), (3) and (7);

B. Twenty five percent (25%) of the proceeds of this action to the Relators if the State of Illinois elects to intervene, and thirty percent (30%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

COUNT VII

(ILLINOIS EX REL. LUTZ AND WEBSTER V ALL DEFENDANTS) ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT 740 Ill. Comp. Stat. § 92/1, *et seq.*

459. Relators re-allege Paragraphs 1 through 458 as though fully set forth herein.

460. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act.

461. By virtue of the acts described above, Defendants knowingly offered and/or paid remuneration to physicians to induce the procurement of patients for Defendants' laboratory testing services for which Defendants could file claims for payment from the patients' insurers. *See* 740 Ill. Comp. Stat. § 92/5(a).

462. Defendants knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

463. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in Illinois, or for patients in Illinois covered by those insurers, to approve or pay such false and fraudulent claims.

464. By virtue of the acts described above, the Defendants conspired to violate the Illinois Insurance Claims Fraud Prevention Act and each patient's private health insurance contract.

465. The private insurers in Illinois, or those insurers that covered patients in Illinois, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendants, paid and continue to pay the claims that are non-payable as a result of Defendants' illegal conduct.

466. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their respective obligations to return overpayments to these private insurance companies.

467. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

468. Each claim for reimbursement that was a result of the Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

469. The State of Illinois is entitled to the maximum penalty of $10,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages that the private insurance companies have sustained because of Defendants' actions, plus a civil penalty of not less than $5,000.00 and not more than $10,000.00 for each violation of 740 Ill. Comp. Stat. §§ 92/5(a) and (b);

B. No less than thirty percent (30%) of the proceeds of this action to the Relators if the State of Illinois elects to intervene, and no less than forty percent (40%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *Qui Tam* Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

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Dated: September 26, 2014

CERTIFICATE OF SERVICE

I hereby certify that on this date I caused a true and correct copy of Plaintiffs/Relators' Severed Second Amended Qui Tam Complaint to be served upon the counsel below via electronic mail and first-class mail:

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Dated: September 26, 2014

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INDEX OF EXHIBITS TO COMPLAINT

Exhibit A: **Sample of Claims for Which Defendants Billed Government**

Exhibit B: **Sample of Claims for Which HDL Billed Government Programs**

Exhibit C: **Sample of Claims for Which Singulex Billed Government Programs**

EXHIBIT "A"

Exhibit A: Sample of Claims for Which Defendants Billed Government

Patient Initials	Program	Date of Service
DDF	Medicare	3/4/2010 (per HDL report)
LJE	Medicare	11/2/2010 (per HDL draw log)
JJ	Medicare, Blue Cross Blue Shield S.C. State Employee Plan	11/8/2010 (per HDL draw log)
MLM	Medicare	11/24/2010 (per HDL draw log)
CEF	Medicare, Medicaid	9/6/2011 (per practice encounter sheet, Singulex draw log)
LJE	Medicare	1/4/2012 (per HDL draw log)
COS	Medicare, Blue Cross Blue Shield S.C. State Employee Plan	1/19/2012 (per HDL draw log)
MPG	Medicare	5/10/2012 (per Singulex report)
SWC	Tricare/CHAMPUS	5/2012 (per Singulex draw log)
RME	Medicare	5/2012 (per Singulex draw log)
BAG	Tricare/CHAMPUS	6/2012 (per Singulex draw log)
LPM	Medicare	7/2012 (per Singulex draw log)

EXHIBIT "B"

Exhibit B: Sample of Claims for Which HDL Billed Government Programs

Patient Initials	Program	Date of Service
DDF	Medicare	6/15/2010 (per HDL report)
LPM	Medicare	9/7/2010 (per HDL draw log)
DDF	Medicare	9/8/2010 (per HDL report)
COS	Medicare, Blue Cross Blue Shield S.C. State Employee Plan	10/4/2010 (per HDL draw log)
HC	Medicare, Tricare/CHAMPUS	10/20/2010 (per Singulex draw log)
LC	Medicare, Tricare/CHAMPUS	11/22/2010 (per HDL draw log)
DLM	Medicare	11/23/2010 (per HDL draw log)
LB	Medicare, Tricare/CHAMPUS	12/15/2010 (per HDL report)
ESZ	Medicare	1/4/2011 (per Medicare Summary Notice; claim processed 1/25/2011)
DDF	Medicare	1/5/2011 (per HDL report)
DDF	Medicare	5/10/2011 (per HDL report)
MPG	Medicare	9/26/2011 (per HDL report)
MPG	Medicare	1/17/2012 (per HDL report)
DGD	Medicare	1/19/2012 (per HDL draw log)
MPG	Medicare	5/14/2012 (per HDL report)
MPG	Medicare	10/15/2012 (per HDL report)
CD	Medicare, Medicaid	11/6/2012 (per HDL report)

EXHIBIT "C"

Exhibit C: Sample of Claims for Which Singulex Billed Government Programs

Patient Initials	Program	Date of Service
DDF	Medicare	9/8/2010 (per Singulex report)
DDF	Medicare	1/4/2011 (per Singulex report)
DDF	Medicare	5/11/2011 (per Singulex report)
DDF	Medicare	8/29/2011 (per Singulex report)
MPG	Medicare	9/26/2011 (per Singulex report)
EAD	Medicare, Medicaid	9/26/2011 (per Singulex draw log)
MPG	Medicare	1/17/2012 (per Singulex report)
SWC	Tricare/CHAMPUS	2/2012 (per Singulex draw log)
HC	Medicare, Tricare/CHAMPUS	5/2012 (per Singulex draw log)
COS	Medicare, Blue Cross Blue Shield S.C. State Employee Plan	5/2012 (per Singulex draw log)
MLM	Medicare	6/2012 (per Singulex draw log)
DLM	Medicare	6/2012 (per Singulex draw log)